SMG 1290.1a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drugs Evaluation and Research

Office of Generic Drugs

Effective Date: December 14, 2018

1. Office of Generic Drugs (DCDM).

A. Oversees the development and implementation of standards for the safety and effectiveness of generic drugs.

B. Reviews and evaluates Abbreviated New Drug Applications (ANDAs) and their amendments or supplements and determines approvability.

C. Establishes bioequivalency specifications for drug products and develops guidelines for bioequivalency reviews, industry protocols, and studies.

D. Oversees all aspects of labeling submissions for ANDAs.

2. Clinical Safety Surveillance Staff (DCDM1)

A. Serves as liaison of OGD with the Office of Surveillance and Epidemiology and other drug surveillance organizations within CDER to obtain information relevant to ensuring the safety of generic drugs on the US market.

B. Oversees a team of safety personnel to help coordinate inputs to OGD from OSE, OC and external sources, to ensure accuracy of data inputs and assist in gathering needed decision makers within CDER to act on potential emerging safety signals.

C. Coordinates all tracked safety issues.

3. Program Management and Analysis Staff (DCDM2)

A. Provides leadership and guidance to personnel within the Office of Generic Drugs 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.

4. Communications Staff (DCDM3)

A. Oversees and coordinates all communications, including publications and presentations, that emanate from OGD to ensure quality and consistency with OGD, CDER and agency policies for communication.

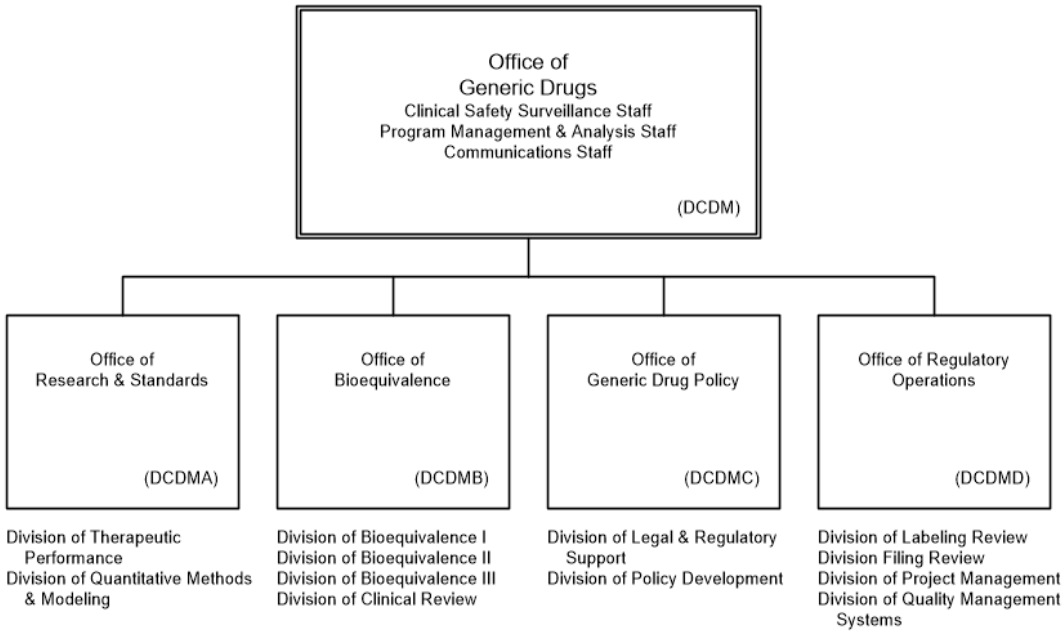
B. Serves as media liaison responsible for all media interactions, and connection to the Office of Communications.

C. Serves as point of contact for OGD in heading communications of generic drug safety issues within and outside of CDER.

5. Authority and Effective Date.

The functional statements for the Office of Generic Drugs 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 Drug Evaluation and Research
Office of Generic Drugs



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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 organizational structures depicting all the organizational structures reporting to the Director.

Office of Generic Drugs (DCDM).

These organizations report to the Office of Generic Drugs:
Clinical Safety Surveillance Staff'
Program Management & Analysis Staff
Communications Staff
Office of Research & Standards (DCDMA)
Office of Bioequivalence (DCDMB)
Office of Generic Drug Policy (DCDMC)
Office of Regulatory Operations (DCDMD)

These organizations report to the Office of Research & Standards:
Division of Therapeutic Performance (DCDMAA)
Division of Quantitative Methods & Modeling (DCDMAB)

These organizations report to the Office of Bioequivalence:
Division of Bioequivalence I (DCDMBA)
Division of Bioequivalence II (DCDMBB)
Division of Bioequivalence III (DCDMBC)
Division of Clinical Review (DCDMBD)

These organizations report to the Office of Generic Drug Policy:
Division of Legal & Regulatory Support (DCDMCA)
Division of Policy Development (DCDMCB)

These organizations report to the Office of Regulatory Operations:
Division of Labeling Review (DCDMDA)
Division of Filing Review (DCDMDB)
Division of Project Management (DCDMDC)
Division of Quality Management Systems (DCDMDD)

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