SMG 1263.1

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 New Drugs

Effective Date: September 25, 2019

1. Office of New Drugs (DCDG).

A. Develops and implements the Center's review management and scientific policies, including user fee policies, pertaining to the drug review process.

B. Reviews Investigational New Drug (IND) applications for all classes of drug and therapeutic products for human use with the exception of generic drug applications and recommends appropriate action with respect to safety and effectiveness of clinical trials.

C. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) for drug products and Biological License Applications (BLAs) for human use. (In this document, the term NDA subsumes BLA, as well).

D. Coordinates and/or reviews and decides on the appropriate action, including approval or disapproval, of all applications for Over-the-Counter (OTC) drug products, OTC drug monographs, prescription drug switches to OTC drug status, and other OTC-related drug products, except for generic drug applications.

E. Develops and implements standards for the safety and effectiveness of prescription drug and therapeutic products for human use and (OTC) drugs.

F. Incorporates data from the Food and Drug Administration (FDA), surveillance programs conducted to collect and evaluate the effects and use trends of marketed drug and therapeutic products.

G. Provides direction and policy formulation for pharmacology/toxicology-related issues for the Center.

H. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of the labeling, clinical

experience and reports submitted by IND sponsors, by NDA applicants, and from other sources.

I. Partners with other FDA components, Department of Health and Human Services organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of drug products to carry out these functions.

J. Oversees the FDA's Radioactive Drug Research Committees Program through the Office of Oncologic Diseases.

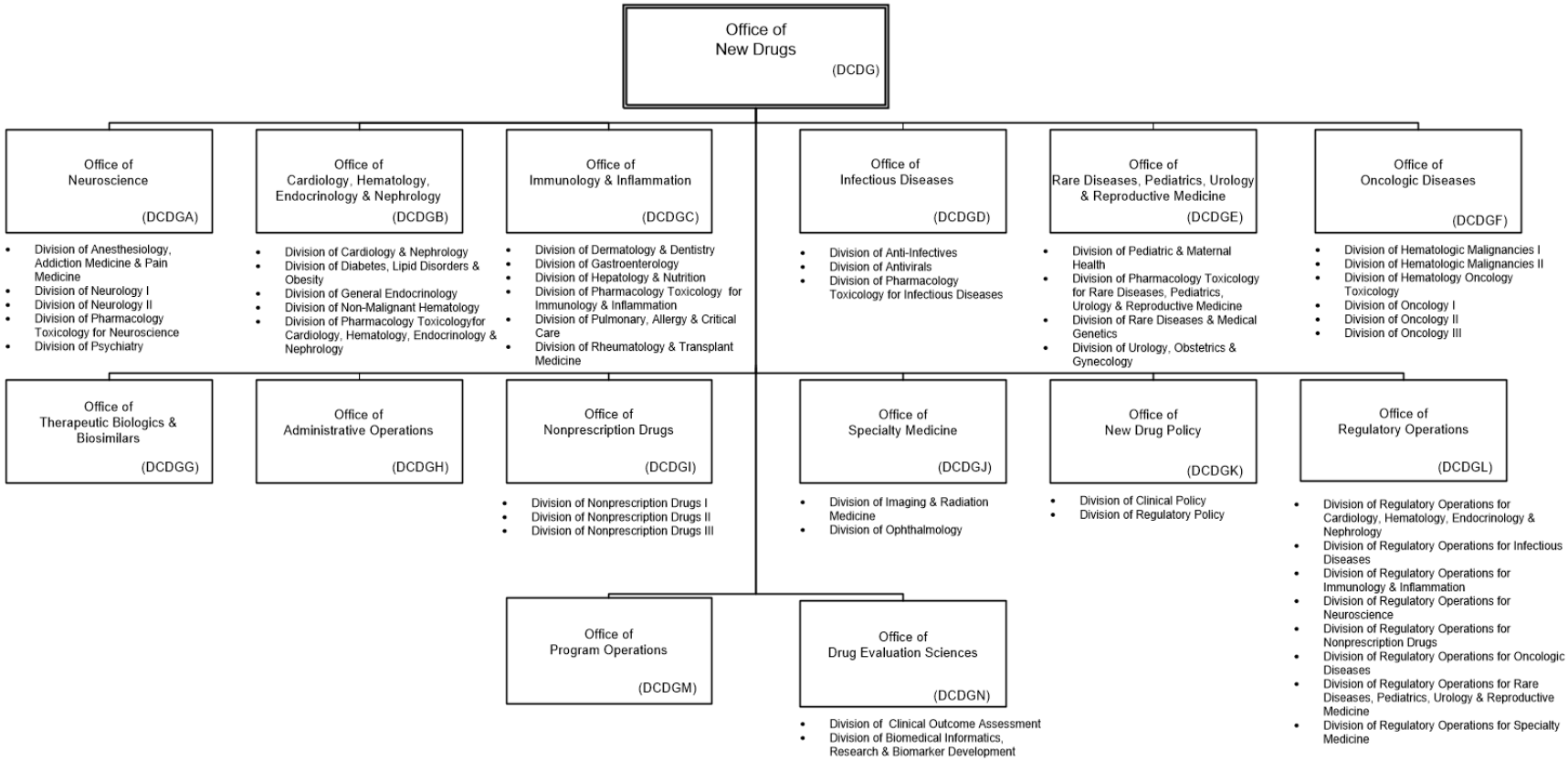
K. Develops in coordination with other FDA components guidance for staff, sponsors and the public that describes the FDA's interpretation of or policy on regulatory issues that involve the Office of New Drugs (OND) offices.

L. Provides oversight of OND's Clinical Data Scientist program, which provides support to OND review divisions in the form of safety data sufficiency and integrity assessments, preliminary safety analyses, the preparation of standardized safety tables and figures, safety data verification in clinical study reports, integrated summary of safety, and draft labeling, exploratory/in-depth safety analyses during the review process.

2. Authority and Effective Date.

The functional statements for the Office of New Drugs were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New 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 New Drugs organization structure depicting all the organizational structures reporting to the Director.

Office of New Drugs (DCDG).

These organizations report to the Office of New Drugs:
Office of Neuroscience (DCDGA)
Office of Cardiology, Hematology, Endocrinology, & Nephrology (DCDGB)
Office of Immunology & Inflammation (DCDGC)
Office of Infectious Diseases (DCDGD)
Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGE)
Office of Oncologic Diseases (DCDGF)
Office of Therapeutic Biologics & Biosimilars (DCDGG)
Office of Administrative Operations (DCDGH)
Office of Nonprescription Drugs (DCDGI)
Office of Specialty Medicine (DCDGJ)
Office of New Drug Policy (DCDGK)
Office of Regulatory Operations (DCDGL)
Office of Program Operations (DCDGM)
Office of Drug Evaluation Science (DCDGN)

These organizations report to the Office of Neuroscience:
Division of Cardiovascular & Renal Products
Division of Neurology Products
Division of Psychiatry Products

These organizations report to the Office of Cardiology, Hematology, Endocrinology, & Nephrology:
Division of Metabolism & Endocrinology Products
Division of Pulmonary, Allergy & Rheumatology Products
Division of Anesthesia, Analgesia & Addiction Products

These organizations report to the Office of Immunology & Inflammation:
Division of Gastroenterology & Urologic Products
Division of Bones, Reproductive & Urologic Products
Division of Dermatology & Dental Products

These organizations report to the Office of Infectious Diseases:
Division of Anti-Infective Products
Division of Anti-Viral Products

Division of Transplant & Ophthalmology Products

These organizations report to the Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine:
Division of Nonprescription Drug Products
Division of Medical Imaging Products
Division of Pediatrics & Maternal Health

These organizations report to the Office of Oncologic Diseases:
Division of Oncology I
Division of Hematologic Malignancies I
Division of ncology II
Division of Hematology Oncology Toxicology
Division of Oncology III
Division of Hematology Malignancies II

These organizations report to the Office of Therapeutic Biologics & Biosimilars:
Policy Staff
Scientific Staff

These organizations report to the Office of Administrative Operations:
Administrative Analysis Staff
Administrative Operations Staff 1
Administrative Operations Staff 2
Administrative Operations Staff 3
Administrative Operations Staff 4
Administrative Operations Staff 5
Financial Services Staff

These organizations report to the Office of Nonprescription Drugs:
Nonprescription Drugs Pharmacology Toxicology Staff
Division of Nonprescription Drugs I
Division of Nonprescription Drugs II

These organizations report to the Office of Specialty Medicine:
Division of Ophthalmology
Division of Imaging & Radiation Medicine

These organizations report to the Office of New Drug Policy:
Division of Clinical Policy
Division of Regulatory Policy

These organizations report to the Office of Regulatory Operations:
Division of Regulatory Operation for Infectious Disease
Division of Regulatory Operations for Oncologic Disease
Division of Regulatory Operations for Nonprescription Drugs

Division of Regulatory Operations for Neuroscience
Division of Regulatory Operations for Cardiology, Hematology, Endocrinology & Nephrology
Division of Regulatory Operations for Immunology & Inflammation
Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine
Division of Regulatory Operations for Specialty Medicine

These organizations report to the Office of Program Operations:
Executive Operations Staff
Business Process & Analysis Staff
Learning & Talent Development Staff
Program Development, Implementation & Management Staff

These organizations report to the Office of Drug Evaluation Science:
Division of Clinical Outcome Assessment
Division of Biomedical Informatics, Research & Biomarker Development

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