SMG 1260.1

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

Effective Date: September 25, 2019

1. Center for Drug Evaluation and Research (DCD).

A. Develops Food and Drug Administration (FDA) policy with regard to the safety, effectiveness, and labeling of all drugs and therapeutic products for human use.

B. Reviews and evaluates new drug applications biological license applications and investigational new drug applications.

C. Develops and implements standards for the safety and effectiveness of all over-the-counter drugs.

D. Monitors the quality of marketed drug products through product testing, surveillance, and compliance programs.

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

F. Develops and promulgates guidelines on Current Good Manufacturing Practices for use by the drug industry.

G. Develops and disseminates information and educational material dealing with drug products to the medical community and the public in coordination with the Office of the Commissioner.

H. Conducts research and develops scientific standards on the composition, quality, safety, and effectiveness of human drugs and therapeutic products.

I. Collects and evaluates information on the effects and use trends of marketed drug therapeutic products.

J. Monitors prescription drug advertising and promotional labeling to assure their accuracy and integrity.

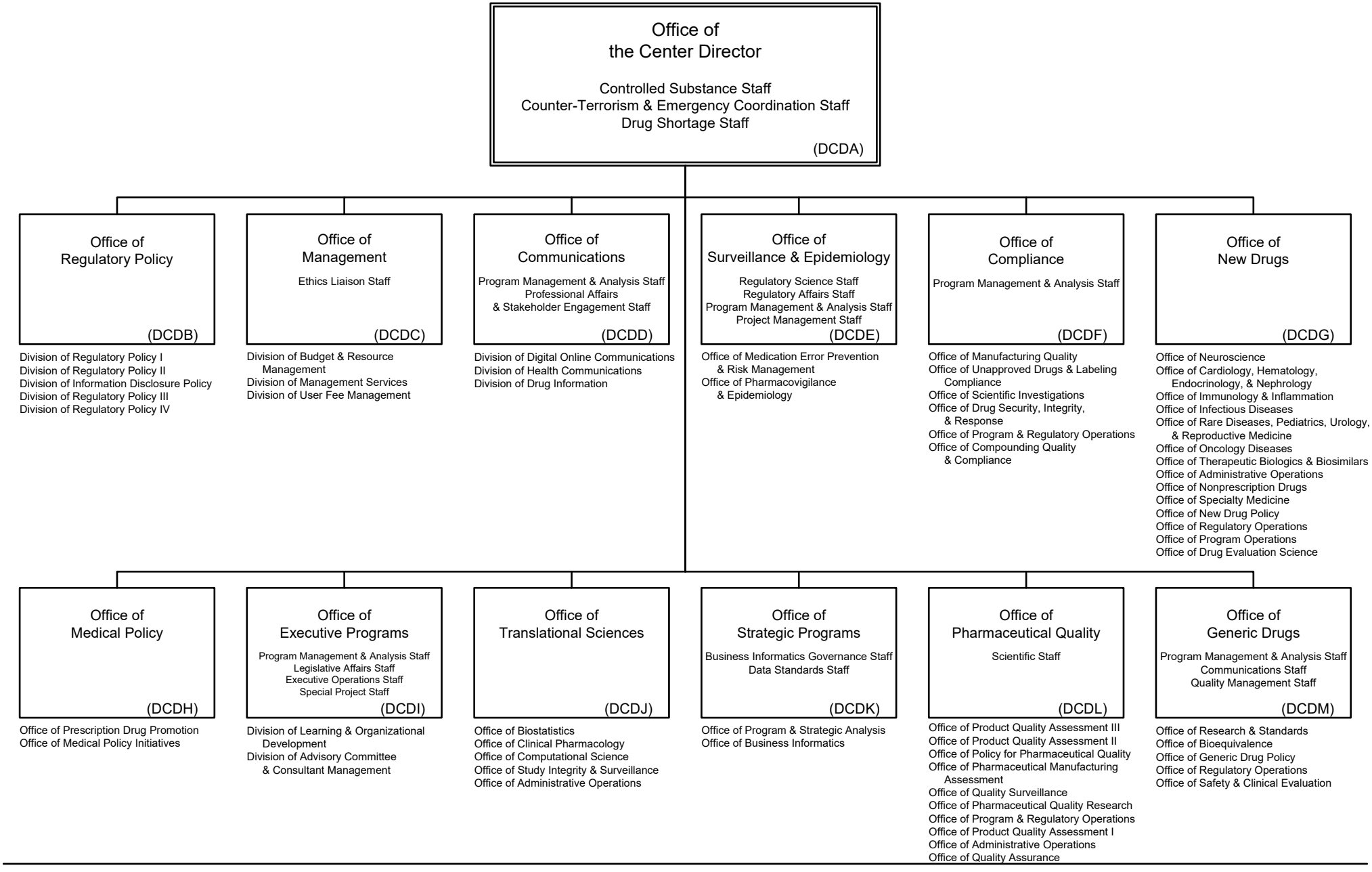
K. Analyzes data on accidental poisonings and disseminates toxicity and treatment information on household products and medicines.

L. Cooperates with other FDA components, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of drug products.

2. Authority and Effective Date.

The functional statements for the Center for Drug Evaluation and Research were approved by the Secretary of Health and Human Services on August 26, 2019, and effective on September 25, 2019.

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



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Organizations and Functions
Effective Date: October 10, 2023

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

Office of the Center Director (DCDA)
Office of Regulatory Policy (DCDB)
Office of Management (DCDC)
Office of Communications (DCDD)
Office of Surveillance and Epidemiology (DCDE)
Office of Compliance (DCDF)
Office of New Drugs (DCDG)
Office of Medical Policy (DCDH)
Office of Executive Programs (DCDI)
Office of Translational Science (DCDJ)
Office of Strategic Programs (DCDK)
Office of Generic Drugs (DCDM)

These organizations report to the Office of the Center Director (DCDA):
Controlled Substances Staff
Counter-Terrorism and Emergency Coordination Staff
Drug Shortage Staff

These organizations report to the Office of Regulatory Policy (DCDB):
Division of Regulatory Policy I
Division of Regulatory Policy II
Division of Information Disclosure Policy
Division of Regulatory Policy III
Division of Regulatory Policy IV

These organizations report to the Office of Management (DCDC):
Ethics Liaison Staff
Division of Budget and Resource Management
Division of Management Services
Division of User Fee Management

These organizations report to the Office of Communications (DCDD):
Program Management and Analysis Staff
Professional Affairs and Stakeholder Engagement Staff
Division of Digital Online Communications
Division of Health Communications
Division of Drug Information

These organizations report to the Office of Surveillance and Epidemiology (DCDE):
Regulatory Science Staff
Regulatory Affairs Staff
Program Management and Analysis Staff
Project Management Staff
Office of Medical Error Prevention and Risk Management
Office of Pharmacovigilance and Epidemiology

These organizations report to the Office of Compliance (DCDF):
Program Management and Analysis Staff
Office of Manufacturing Quality
Office of Unapproved Drugs and Labeling Compliance
Office of Scientific Investigations
Office of Drug Security, Integrity, and Response
Office of Program and Regulatory Operations
Office of Compounding Quality and Compliance

These organizations report to the Office of New Drugs (DCDG):
Office of Neuroscience
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Office of Immunology and Inflammation
Office of Infectious Diseases
Office of Rare Diseases, Pediatrics, Urology, and Reproductive Medicine
Office of Oncology Diseases
Office of Therapeutic Biologics and Biosimilars
Office of Administrative Operations
Office of Nonprescription Drugs
Office of Specialty Medicine
Office of New Drug Policy
Office of Regulatory Operations
Office of Program Operations
Office of Drug Evaluation Science

These organizations report to the Office of Medical Policy (DCDH):
Office of Prescription Drug Promotion
Office of Medical Policy Initiatives

These organizations report to the Office of Executive Programs (DCDI):
Program Management and Analysis Staff
Legislative Affairs Staff
Executive Operations Staff
Special Project Staff
Division of Learning and Organizational Development
Division of Advisory Committee and Consultant Management

These organizations report to the Office of Translational Sciences (DCDJ):
Office of Biostatistics
Office of Clinical Pharmacology
Office of Computational Science
Office of Study Integrity and Surveillance
Office of Administrative Operations

These organizations report to the Office of Strategic Programs (DCDK):
Business Informatics Governance Staff
Data Standards Staff
Office of Program and Strategic Analysis
Office of Business Informatics

These organizations report to the Office of Pharmaceutical Quality (DCDL):
Scientific Staff
Office of Product Quality Assessment III
Office of Product Quality Assessment II
Office of Policy for Pharmaceutical Quality
Office of Pharmaceutical Manufacturing Assessment
Office of Quality Surveillance
Office of Pharmaceutical Quality Research
Office of Program & Regulatory Operations
Office of Product Quality Assessment I
Office of Administrative Operations
Office of Quality Assurance

These organizations report to the Office of Generic Drugs (DCDM):
Program Management and Analysis Staff
Communications Staff
Quality Management Staff
Office of Research and Standards
Office of Bioequivalence
Office of Generic Drug Policy
Office of Regulatory Operations
Office of Safety and Clinical Evaluation