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.

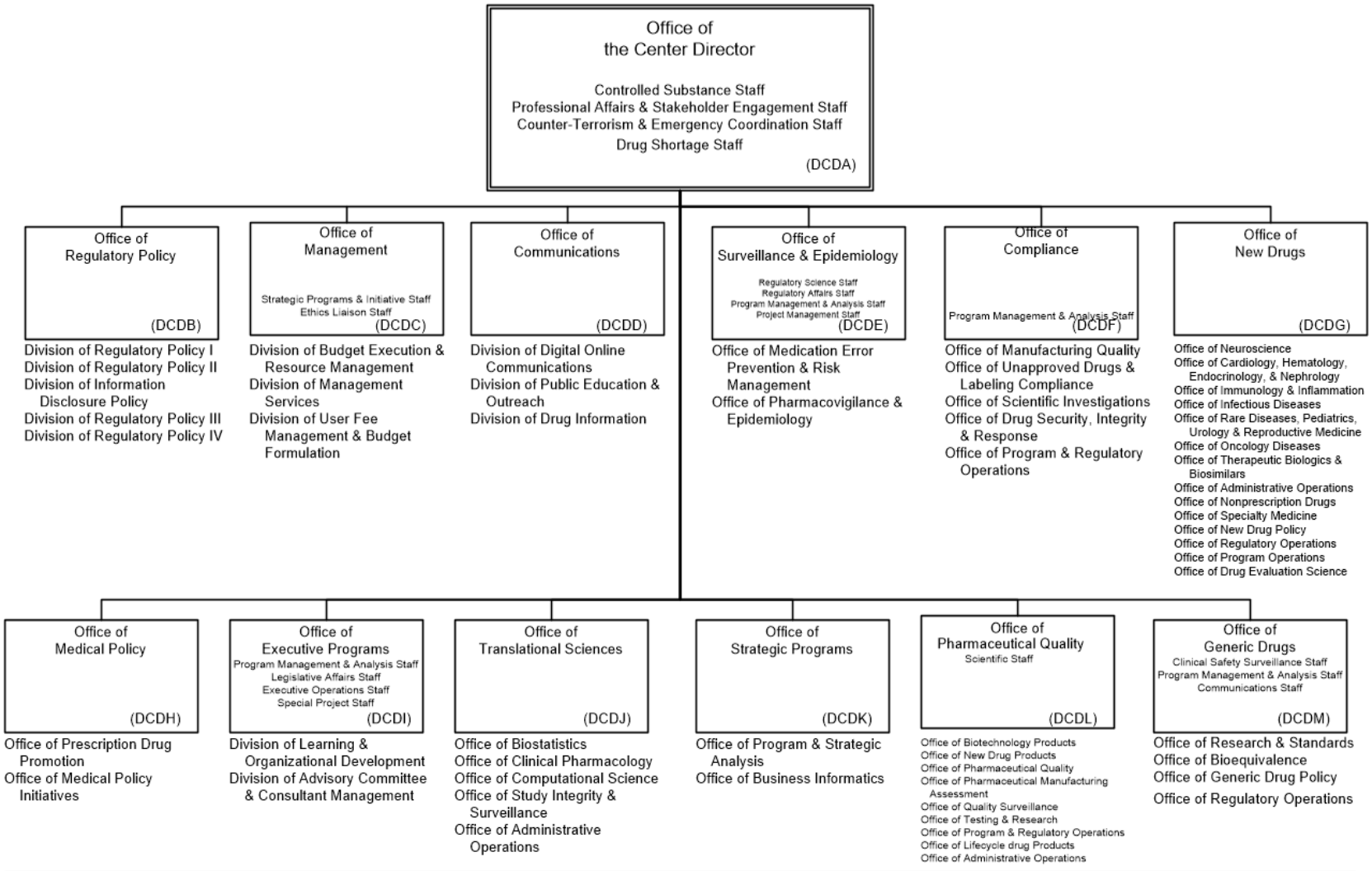
K. Analyzes data on accidental poisonings and disseminates toxicity and treatment information on household products and medicines.

L. Cooperates with other Agency components of FDA, 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 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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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:

Center for Drug Evaluation and Research (DCD).

These organizations report to the Center for Drug Evaluation and Research:

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

These organizations report to the Office of Regulatory Policy:
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:
Strategic Programs & Initiative Staff
Ethics Liaison Staff
Division of Budget Execution & Resources Management
Division of Management Services
Division of User Fee Management & Budget Formulation

These organizations report to the Office of Surveillance & Epidemiology:
Regulatory Science Staff
Regulatory Affairs Staff
Program Management & Analysis Staff
Office of Medication Error Prevention & Risk Management
Office of Pharmacovigilance & Epidemiology

These organizations report to the Office of Compliance:
Program Management & Analysis Staff
Office of Manufacturing Quality
Office of Unapproved Drugs & Labeling Compliance
Office of Scientific Investigations
Office of Drug Security Integrity & Response
Office of Program & Regulatory Operations

These organizations report to the Office of New Drugs:
Office of Neuroscience
Office of Cardiology, Hematology, Endocrinology, & Nephrology
Office of Immunology & Inflammation
Office of Infectious Diseases
Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine
Office of Oncologic Diseases
Office of Therapeutic Biologics & 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
Office of Administrative Operations

These organizations report to the Office of Medical Policy:
Office of Prescription Drug Promotion
Office of Medical Policy Initiatives
These organizations report to the Office of Executive Programs:
Program Management & Analysis Staff
Legislative Affairs Staff
Executive Operations Staff
Special Project Staff
Division of Learning & Organizational Development
Division of Advisory Committee & Consultant Management

These organizations report to the Office of Transitional Sciences:
Office of Biostatistics
Office of Clinical Pharmacology
Office of Computational Science
Office of Study Integrity & Surveillance
Office of Administrative Operations

These organizations report to the Strategic Programs:
Office of Program & Strategic Analysis

Office of Business Informatics

These organizations report to the Office of Pharmaceutical Quality:
Scientific Staff
Office of Biotechnology Products
Office of New Drug Products
Office of Policy for Pharmaceutical Quality
Office of Pharmaceutical Manufacturing Assessment
Office of Quality Surveillance
Office of Testing & Research
Office of Program & Regulatory Operations
Office of Lifecycle Drug Products
Office of Administrative Operations

These organizations report to the Office of Generic Drugs:
Clinical Safety Surveillance Staff
Program Management & Analysis Staff
Communications Staff
Office of Research & Standards
Office of Bioequivalence
Office of Generic Drug Policy
Office of Regulatory Operations

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