



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research's (CDER), Office of Surveillance and Epidemiology (OSE) and Office of New Drugs (OND) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on November 20, 2014.

FOR FURTHER INFORMATION CONTACT: Jennifer Wade, Acting Director, Division of Reorganizations and Delegations of Authority, Office of Budget, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993, 240-731-0192.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganization of CDER's OSE and OND.

The purpose of this reorganization is to strengthen OSE and OND's ability to support FDA's mission and streamline its operations.

Within OSE, the newly elevated Office of Regulatory Science (ORS) will provide scientific and technical leadership in pharmacovigilance informatics, regulatory informatics

systems, and science operations, including securing access to necessary data sources for drug product surveillance operations and overseeing applied research studies. While the newly elevated Office of Regulatory Operations (ORO) will manage strategic and operational projects associated with drug safety, particularly with drug safety reviews. The Executive Operations Staff (EOS) will liaise with stakeholders through the Center and the FDA as well as with external groups as appropriate to activities within OSE, coordinate executive operations of Office leadership, and support organizational development activities for OSE staff.

Within OND, this overall reorganization proposal addresses key priorities for the country as exhibited by their direct connection to multiple acts of Congress or declarations from the executive branch, including the Over-The-Counter (OTC) Monograph Reform, Biosimilars User Fee Act III (BsUFA III), Opioids Public Health Emergency Declaration, and the SUPPORT Act. Through this reorganization the FDA will be best organized and positioned to address the critical workload, policy and oversight demands expected in the space of biosimilars, OTC drug products, rare disease drug development, and opioids.

The FDA's CDER has been restructured as follows:

DCDE ORGANIZATION. The CDER's OSE is headed by the Director, OSE and includes the following:

Office of Surveillance and Epidemiology (DCDE)

Program Management and Analysis Staff (DCDE3)

Executive Operations Staff (DCDE5)

Office of Medication Error Prevention and Risk Management (DCDEA)

Division of Medication Error Prevention and Analysis (DCDEAA)

Division of Risk Management (DCDEAB)

Office of Pharmacovigilance and Epidemiology (DCDEB)

Division of Epidemiology I (DCDEBA)

Division of Epidemiology I (DCDEBB)

Division of Pharmacovigilance I (DCDEBC)

Division of Pharmacovigilance I (DCDEBD)

Office of Regulatory Science (DCDEC)

Division of Regulatory Science and Applied Research (DCDECA)

Division of Pharmacovigilance Informatics and Operations Management (DCDECB)

Office of Regulatory Operations (DCDED)

Division of Regulatory Project Management I (DCDEDA)

Division of Regulatory Project Management II (DCDEDB)

DCDG ORGANIZATION. The CDER's OND is headed by the Director, OND and includes the following organizational units:

Office of Neuroscience (DCDGA)

Division of Neurology I (DCDGAB)

Division of Neurology II (DCDGAC)

Division of Psychiatry (DCDGAD)

Division of Pharmacology/Toxicology for Neuroscience (DCDGAF)

Office of Cardiology, Hematology, Endocrinology, & Nephrology (DCDGB)

Division of Metabolism & Endocrinology Products (DCDGBA)

Division of Pulmonary, Allergy & Rheumatology Products (DCDGBB)

Division of Anesthesia, Analgesia & Addiction Products (DCDGBC)

Office of Immunology & Inflammation (DCDGC)

Division of Gastroenterology & Urologic Products (DCDGCA)

Division of Bones, Reproductive & Urologic Products (DCDGCB)

Division of Dermatology & Dental Products (DCDGCC)

Office of Infectious Diseases (DCDGD)

Division of Anti-Infective Products (DCDGDA)

Division of Anti-Viral Products (DCDGDB)

Division of Transplant & Ophthalmology Products (DCDGDC)

Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGE)

Division of Pediatrics and Maternal Health (DCDGEC)

Division of Pharmacology/Toxicology of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (DCDGED)

Division of Urology, Obstetrics, and Gynecology (DCDGEF)

Division of Rare Diseases (DCDGEG)

Division of Medical Genetics (DCDGEH)

Office of Oncologic Diseases (DCDGF)

Office of Therapeutic Biologics & Biosimilars (DCDGG)

Division of Policy (DCDGGA)

Division of Scientific Review (DCDGGB)

Office of Administrative Operations (DCDGH)

Administrative Analysis Staff (DCDGH1)

Administrative Operations Staff 1 (DCDGH2)

Administrative Operations Staff 2 (DCDGH3)

Administrative Operations Staff 3 (DCDGH4)

Administrative Operations Staff 4 (DCDGH5)

Administrative Operations Staff 5 (DCDGH6)

Financial Services Staff (DCDGH7)

Office of Nonprescription Drugs (DCDGI)

Nonprescription Drugs Pharmacology Toxicology Staff (DCDGI1)

Division of Nonprescription Drugs I (DCDGIA)

Division of Nonprescription Drugs II (DCDGIB)

Division of Nonprescription Drugs III (DCDGIC)

Division of Pharmacology/Toxicology for Nonprescription Drugs (DCDGID)

Office of Specialty Medicine (DCDGJ)

Division of Ophthalmology (DCDGJA)

Division of Imaging & Radiation Medicine (DCDGJB)

Office of New Drug Policy (DCDGK)

Division of Clinical Policy (DCDGKA)

Division of Regulatory Policy (DCDGKB)

Office of Regulatory Operations (DCDGL)

Division of Regulatory Operation for Infectious Disease (DCDGLA)

Division of Regulatory Operations for Oncologic Disease (DCDGLB)

Division of Regulatory Operations for Nonprescription Drugs (DCDGLC)

Division of Regulatory Operations for Neuroscience (DCDGLD)

Division of Regulatory Operations for Cardiology, Hematology, Endocrinology & Nephrology (DCDGLE)

Division of Regulatory Operations for Immunology & Inflammation (DCDGLF)

Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGLG)

Division of Regulatory Operations for Specialty Medicine (DCDGLH)

Division of Regulatory Operations for Pain, Anesthesia, and Addiction Medicine (DCDGLI)

Office of Program Operations (DCDGM)

Executive Operations Staff (DCDGM1)

Business Process & Analysis Staff (DCDGM2)

Learning & Talent Development Staff (DCDGM3)

Program Development, Implementation & Management Staff (DCDGM4)

Office of Drug Evaluation Science (DCDGN)

Division of Clinical Outcome Assessment (DCDGNA)

Division of Biomedical Informatics, Research & Biomarker Development (DCDGNB)

Office of Pain, Anesthesia, and Addiction Medicine (DCDGO)

Division of Anesthesia and Pain Medicine (DCDGOA)

Division of Substance Use Disorder Medicine (DCDGOB)

Division of Pharmacology/Toxicology for Pain, Anesthesia, and Addiction Medicine
(DCDGOC)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at:

<https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>

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