4164-01-P

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 (FDA), Center of Drug Evaluation and Research (CDER) has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Edwin Echegoyen, Acting Director, Office of Management/Executive Officer, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Silver Spring, MD 20993, 301-796-3300.

I. Summary

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; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Center of Drug Evaluation and Research.

This reorganization consists of the following Offices: Office of New Drugs (OND), Office of Translational Science (OTS), and Office of Pharmaceutical Quality (OPQ) within the Center for Drug Evaluation and Research and revises their functional statements. The proposed organizational changes align with the ReImagine HHS strategic shift moving to the 21st century: Maximizing Talent, Integrated Assessments, Benefit Risk Monitoring, and Leveraging the Power of Data. CDER will meet the definition of Maximizing Talent by focusing on growing our scientific leadership. This will result in clearly designed pathways to regulatory approval and enhanced emphasis on multidisciplinary teams. The proposed reorganization will integrate assessments to critically, collaboratively, and consistently assess whether information in submissions meets statutory and regulatory requirements. OND, OPQ, and OTS will establish Benefit-Risk Monitoring to unify the post-market safety surveillance framework leading to operational excellence by aligning the therapeutic focus. Each of these offices will incorporate Leveraging the Power of Data to provide access to analytical tools and systems to help the reviewers evaluate and interpret submitted data, thereby improving and streamlining the processes which will impact the critical analyses leading to efficiencies and effectiveness in CDER's scientific regulatory review.

Under Part D, FDA, the Center for Drug Evaluation and Research (CDER) has been restructured as follows:

Standard Administrative Codes (SAC). ORGANIZATION--CDER is headed by the Director and includes the following organizational units:

Office of Regulatory Policy (SAC)

Office of Management (SAC)

Office of Communications (SAC)

Office of Compliance (SAC)

Office of Manufacturing Quality (SAC)

Office of Unapproved Drugs and Labeling Compliance (SAC)

Office of Scientific Investigations (SAC)

Office of Program and Regulatory Operations (SAC)

Office of Medical Policy (SAC)

Office of Prescription Drug Promotion (SAC)

Office of Medical Policy Initiatives (SAC)

Office of Translational Sciences (SAC)

Office of Biostatistics (SAC)

Office of Clinical Pharmacology (SAC)

Office of Computational Science (SAC)

Office of Study Integrity and Surveillance (SAC)

Office of Administrative Operations (SAC)

Office of Executive Programs (SAC)

Office of Surveillance and Epidemiology (SAC)

Office of Medication Error Prevention and Risk Management (SAC)

Office of Pharmacovigilance and Epidemiology (SAC)

Office of New Drugs (SAC)

Office of Administrative Operations (SAC)

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

Office of Drug Evaluation Science (SAC)

Office of Immunology & Inflammation (SAC)

Office of Infectious Diseases (SAC)

Office of Neuroscience (SAC)

Office of New Drug Policy (SAC)

Office of Nonprescription Drugs (SAC)

Office of Oncologic Diseases (SAC)

Office of Program Operations (SAC)

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

Office of Regulatory Operations (SAC)

Office of Specialty Medicine (SAC)

Office of Therapeutic Biologics and Biosimilars (SAC)

Office of Strategic Programs (SAC)

Office of Program and Strategic Analysis (SAC)

Office of Business Informatics (SAC)

Office of Generic Drugs (SAC)

Office of Research Standards (SAC)

Office of Bioequivalence (SAC)

Office of Generic Drug Policy (SAC)

Office of Regulatory Operations (SAC)

Office of Pharmaceutical Quality (SAC)

Office of Administrative Operations (SAC)

Office of Biotechnology Products (SAC)

Office of Lifecycle Drug Products (SAC)

Office of New Drug Products (SAC)

Office of Pharmaceutical Manufacturing Assessment (SAC)

Office of Policy for Pharmaceutical Quality (SAC)

Office of Program and Regulatory Operations (SAC)

Office of Quality Surveillance (SAC)

Office of Testing and Research (SAC)

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 SMG can find it on FDA's website at: https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.

(Authority: 44 U.S.C. 3101).

Alex M. Azar, II

Secretary

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