SMG 1268.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF TRANSLATIONAL SCIENCES

Effective Date: 12/10/2012

1. OFFICE OF TRANSLATIONAL SCIENCES (DKKNG).

A. Promotes efficient and informative study designs and data analysis methods to quantitatively evaluate the efficacy, safety, and dosing of drugs through collaboration among the Office of Biostatistics, Office of Clinical Pharmacology, and other offices in the Center for Drug Evaluation and Research (CDER) and centers in the Food and Drug Administration (FDA). Fosters novel drug development strategies through research and application of statistical and mathematical modeling and simulation techniques in the review and analysis of data in the areas of exposure-response, pharmacokinetics, pharmacodynamics, pharmacogenomics, bioequivalence assessment, clinical trials, quantitative risk assessment, toxicology, and product quality assessment.

B. In collaboration with and implemented through the Office of Biostatistics, provides leadership, direction, policy development, and coordination to CDER on statistical, mathematical, and computational aspects of regulatory and scientific review. Provides independent and collaborative statistical evaluations and reviews to all programs and disciplines of CDER in support of the scientific and regulatory review process related to drugs and therapeutic biologics with special attention to the safety and efficacy of these products.

C. In collaboration with and implemented through the Office of Clinical Pharmacology evaluates, recommends, and sets policy for data and information in clinical pharmacology necessary for an evaluation of benefit/risk, including optimal dosing in patients and special programs. Provides advice and recommendations at critical industry meetings, such as End of Phase 2A meetings, and regarding inclusion of clinical pharmacology information in the label of drug products.

D. In collaboration with the Office of Clinical Pharmacology, Office of Biostatistics and other offices in CDER develops existing staff and trains new scientists and medical officers in novel drug development methodologies.

E. Provides leadership, advocacy, direction, scientific skill, coordination, and tracking for all Critical Path (CP) initiatives across CDER in partnership with individual CDER offices. Informs CDER Center Director's Office of CP initiatives and progress. Serves as the initial point of contact and coordination for Critical Path Initiative projects originating inside and outside of CDER/FDA.

F. Communicates and coordinates CDER Critical Path activities with the Office of the Commissioner including: facilitating and participating in public-private partnerships, planning workshops, serving on Critical Path Initiative Steering Committees, making public presentations on Critical Path initiatives, and preparing strategic documents.

G. Catalyzes an interdisciplinary approach to organizational change through collaboration with other disciplines in CDER to enhance integration of Critical Path science in to drug development and regulatory review.

H. Collaborates with the Office of Medical Policy (Clinical Trials Design Group) and other CDER offices to write and issue concept papers/guidance to address methodologies to foster innovative approaches to drug development.

I. Responsible for evaluating and aligning research to support the mission and functions of CDER, including the initiatives of the Critical Path. Coordinates and facilitates CDER research activities by providing oversight and quality assurance for all CDER research activities involving human subjects; guiding and administrating the CDER Regulatory Science Research priorities and grants; and leading and administrating CDER Research Coordinating Committee.

J. Collaborates with the Office of New Drugs, Office of Planning and Informatics and the Office of Business Process Support to develop data repositories that support a knowledge management system for the purpose of enhancing the design and efficient conduct of future clinical studies. This system is designed to improve the quality and consistency of FDA advice to industry, review on Investigational New Drug applications (INDs) and New Drug Applications (NDAs) and the design of research activities.

2. PROGRAM MANAGEMENT AND ANALYSIS STAFF (DKKNG1).

A. Provides leadership, guidance and support services to the Office of Translational Sciences on all aspects of administrative, budget, contracts management, facilities management and provides service and support on human resource, personnel operations services and recruitment activities.

B. Responsible for coordination, development and assessment of policies, procedures, and best practices related to OTS office administration and contract management within OTS.

3. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Director, Center for Drug Evaluation and Research on December 10, 2012.

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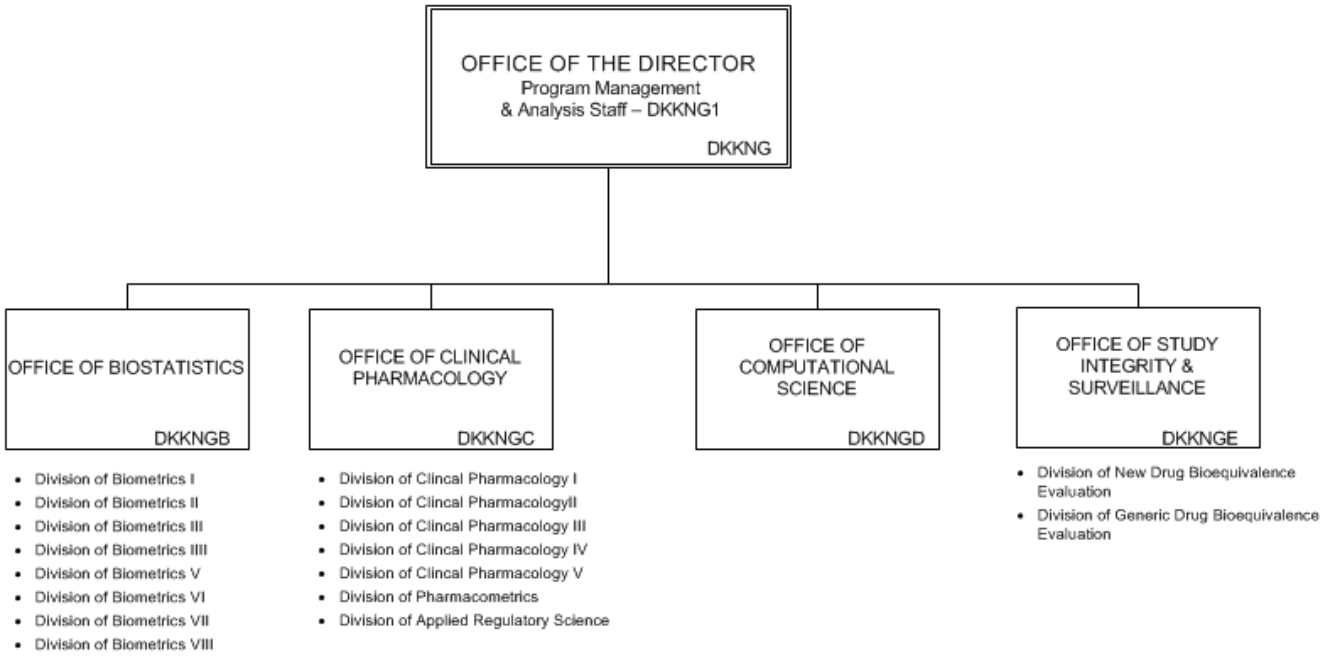

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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Translational Sciences organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNG:

- Program Management & Analysis Staff – DKKNG1

- OFFICE OF BIOSTATISTICS - DKKNGB
  - Division of Biometrics I
  - Division of Biometrics II
  - Division of Biometrics III
  - Division of Biometrics IV
  - Division of Biometrics V
  - Division of Biometrics VI
  - Division of Biometrics VII
  - Division of Biometrics VIII
- OFFICE OF CLINICAL PHARMACOLOGY - DKKNGC
  - Division of Clinical Pharmacology I
  - Division of Clinical Pharmacology II
  - Division of Clinical Pharmacology III
  - Diision of Clinical Pharmacology IV
  - Division of Clinical Pharmacology V
  - Division of Pharmacometrics
  - Division of Applied Regulatory Science

- OFFICE OF COMPUTATIONAL SCIENCE - DKKNGD
- OFFICE OF STUDY INTEGRITY AND SURVEILLANCE - DKKNGE
  - Division of New Drug Bioequivalence Evaluation
  - Division of Generic Drug Bioequivalence Evaluation