SMG 1263.1

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 NEW DRUGS

Effective Date: August 26, 2014

1. OFFICE OF NEW DRUGS (DKKNR)

A. Develops and implements the Center's review management and scientific policies, including user fee policies, pertaining to the drug review process.

B. Reviews investigational new drug applications (INDs) for all classes of drug and therapeutic products for human use with the exception of generic drug applications, and recommends appropriate action with respect to safety and effectiveness of clinical trials.

C. Evaluates for safety and effectiveness and approves new drug applications (NDAs) for drug products and biological license applications (BLAs) for human use. (In this document, the term NDA subsumes BLA, as well).

D. Coordinates and/or reviews and decides on the appropriate action, including approval or disapproval, of all applications for over-the-counter (OTC) drug products, OTC drug monographs, prescription drug switches to OTC drug status, and other OTC-related drug products, with the exception of generic drug applications.

E. Develops and implements standards for the safety and effectiveness of prescription drug and therapeutic products for human use and (OTC) drugs.

F. Incorporates data from the Agency, surveillance programs conducted to collect and evaluate the effects and use trends of marketed drug and therapeutic products.

G. Provides direction and policy formulation for pharmacology/toxicology-related issues for the Center.

H. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of the labeling, clinical

experience and reports submitted by IND sponsors, by NDA applicants, and from other sources.

I. In carrying out these functions, cooperates with other Agency components, other Department of Health and Human Services (DHHS) organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of drug products.

J. Oversees the Agency's Radioactive Drug Research Committees Program through the Office of Oncology Drug Products.

K. Develops in coordination with other Agency components guidance for staff, sponsors and the public that describes the Agency's interpretation of or policy on regulatory issues that involve the Offices of Drug Evaluation (ODEs).

2. PROGRAM MANAGEMENT AND ANALYSIS STAFF (DKKNR3)

Provides leadership, guidance and support services to the Office of New Drugs on all aspects of administrative, budget and facilities management and provides service and support on human resource, personnel operations services and recruitment activities

3. AUTHORITY AND EFFECTIVE DATE

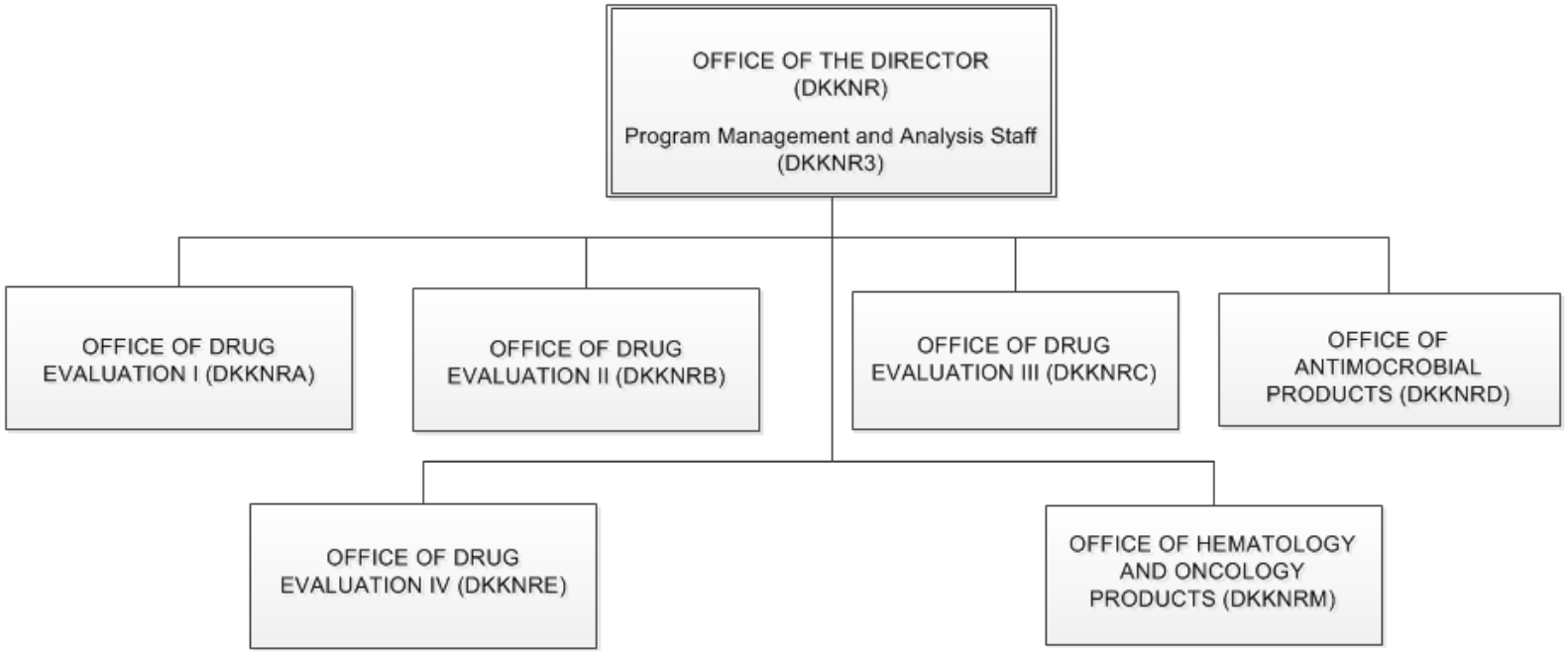
The functional statements for this Office were approved by the Director, Center for Drug Evaluation and Research and effective on August 26, 2014.

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF NEW DRUGS



Staff Manual Guide 1263.1
Organizations and Functions
Effective Date: August 26, 2014

The following header reflects the organizational hierarchy.

FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF NEW DRUGS

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

OFFICE OF THE DIRECTOR:

- Program Management and Analysis Staff

- OFFICE OF DRUG EVALUATION I
- OFFICE OF DRUG EVALUATION II
- OFFICE OF DRUG EVALUATION III
- OFFICE OF ANTIMICROBIAL PRODUCTS
- OFFICE OF DRUG EVALUATION IV
- OFFICE OF HEMATOLOGY AND ONCOLOGY PRODUCTS