SMG 1263.20

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

OFFICE OF DRUG EVALUATION I

Effective Date: 07/08/2011

1. OFFICE OF DRUG EVALUATION I (DKKNRA)

A. Reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials

B. Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based

C. Develops policy and procedures governing the review and evaluation of drug investigations and NDAs

D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office

E. Performs consulting medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center

F. Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by holders of NDAs for products regulated by this Office

G. Monitors, evaluates, and develops policy for prescription drug promotion and labeling

H. Initiates necessary actions to maintain industry compliance with prescription drug advertising and labeling regulations

I. Participates in Agency sponsored consumer and professional educational programs on drug standards

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

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/01/2005	N/a	OC/OO/ OM/OMP	Acting Director, Center for Drug Evaluation and Research
Revision	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

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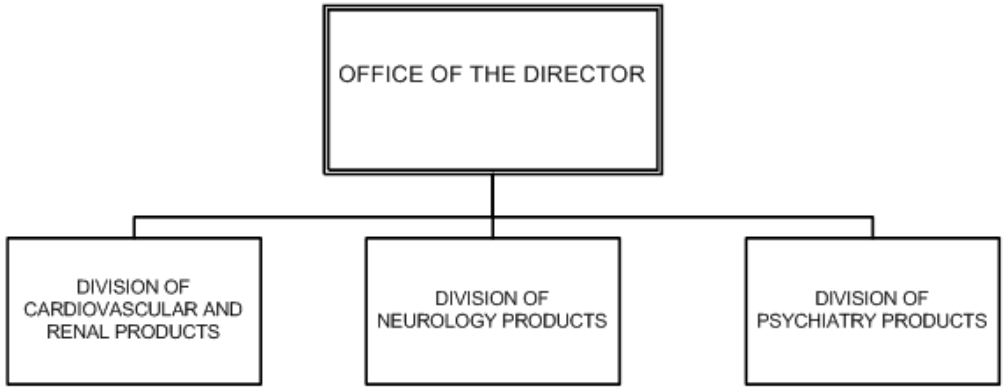

Staff Manual Guide 1263.20
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE DIRECTOR:

- DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS
- DIVISION OF NEUROLOGY PRODUCTS
- DIVISION OF PSYCHIATRY PRODUCTS