SMG 1260.1

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

Effective Date: 07/08/2011

1. CENTER FOR DRUG EVALUATION AND RESEARCH (DKKN)

A. Develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs and therapeutic products for human use

B. Reviews and evaluates new drug applications (NDAs), biological license applications (BLAs) and investigational new drug applications (INDs)

C. Develops and implements standards for the safety and effectiveness of all over-the-counter (OTC) drugs

D. Monitors the quality of marketed drug products through product testing, surveillance, and compliance programs

E. Coordinates with the Center for Biologics Evaluation and Research regarding activities for biological drug products. Such activities include research, compliance, and product review and approval

F. Develops and promulgates guidelines on Current Good Manufacturing Practices for use by the drug industry

G. Develops and disseminates information and educational material dealing with drug products to the medical community and the public in coordination with the Office of the Commissioner

H. Conducts research and develops scientific standards on the composition, quality, safety, and effectiveness of human drugs and therapeutic products

I. Collects and evaluates information on the effects and use trends of marketed drug therapeutic products

J. Monitors prescription drug advertising and promotional labeling to assure their accuracy and integrity

K. Analyzes data on accidental poisonings and disseminates toxicity and treatment information on household products and medicines

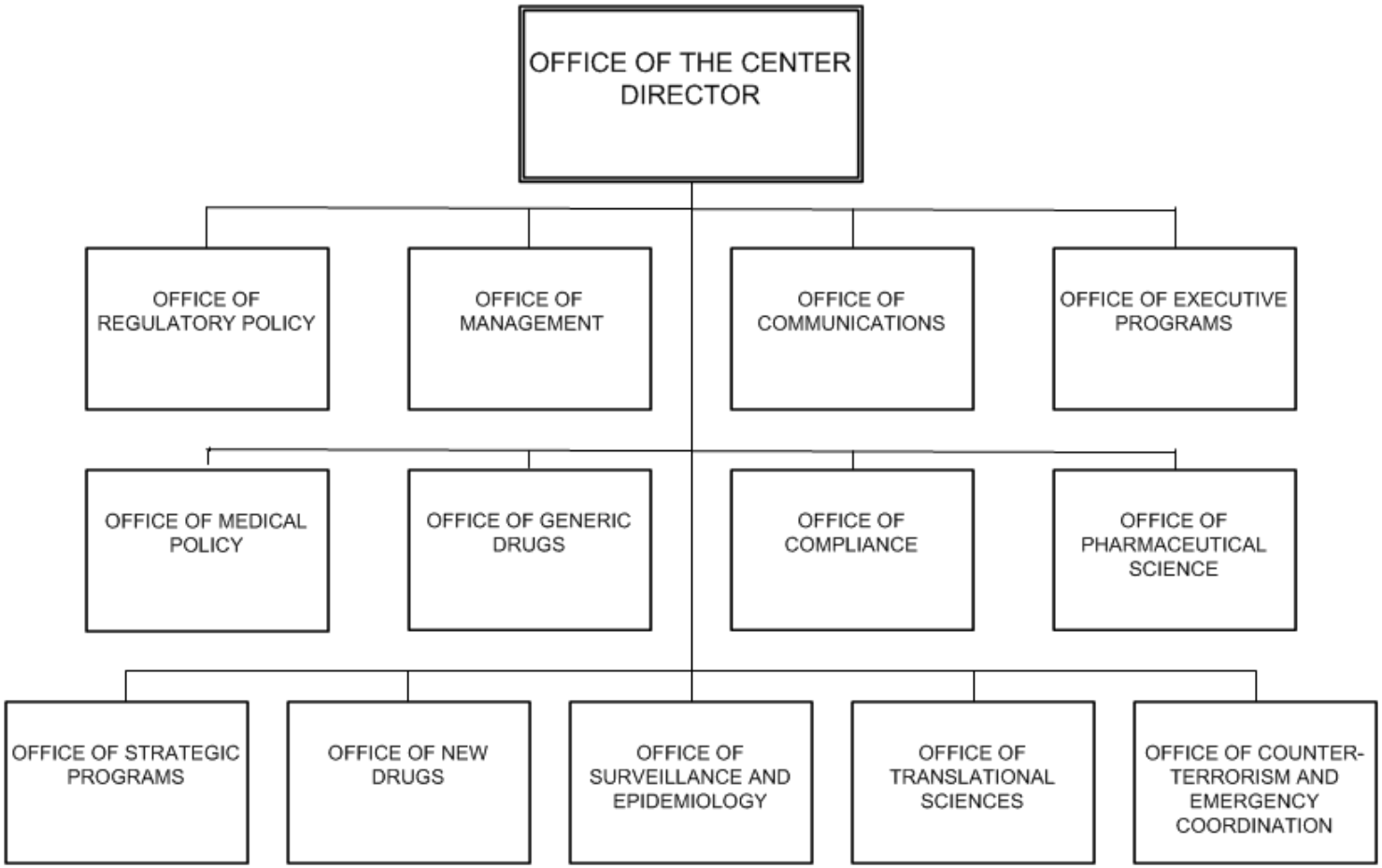
L. In carrying out these functions, cooperates with other Agency components of FDA, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of drug products

2. AUTHORITY AND EFFECTIVE DATE

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	07/08/2011	N/a	CDER/OM	Secretary of Health and Human Services
Change	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH



Staff Manual Guide 1260.1
Organizations and Functions
Effective Date: January 24, 2014

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

OFFICE OF THE DIRECTOR:

- OFFICE OF REGULATORY POLICY
- OFFICE OF MANAGEMENT
- OFFICE OF COMMUNICATIONS
- OFFICE OF EXECUTIVE PROGRAMS
- OFFICE OF MEDICAL POLICY
- OFFICE OF GENERIC DRUGS
- OFFICE OF COMPLIANCE
- OFFICE OF PHARMACEUTICAL SCIENCE
- OFFICE OF STRATEGIC PROGRAMS
- OFFICE OF NEW DRUGS
- OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
- OFFICE OF TRANSLATIONAL SCIENCES
- OFFICE OF COUNTER-TERRORISM AND EMERGENCY COORDINATION