SMG 1261.5

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 SURVEILLANCE AND EPIDEMIOLOGY

Effective Date: 12/10/2012

1. OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY (DKKNO).

A. Provides leadership, direction, planning, budgeting, management and supervision of divisions and staff and pre-marketing and post-marketing risk assessment program operations.

B. Coordinates regulatory efforts with international and national regulatory counterparts.

C. Develops, coordinates and implements post-market risk assessment policies, guidance and interpretations.

D. Initiates regulation development and enhancement.

E. Coordinates and implements policies and initiatives, including information management initiatives across the Agency.

F. Creates and maintains professional and skills training programs for OSE personnel to maintain credentials and certifications in support of surveillance and epidemiological program activities.

G. Plans and tracks goals and objectives of all OSE divisions.

H. Evaluates OSE work products and communications using quality control technology.

I. Coordinate surveillance and epidemiologic program activities with Executive Secretariat, Press Office, and other internal and external groups.

2. REGULATORY SCIENCE STAFF (DKKNO4).

A. Provides leadership, direction, and coordination for OSE regulatory science activities.

B. Develops and manages relationships with outside scientific groups that interface with OSE scientists on a variety of projects that relate to OSE's drug safety mission. These outside groups include academic organizations, private organizations, and other federal agencies.

C. Coordinates the access to large databases for pharmacoepidemiologic and pharmacovigilance studies, as well as, to the outside scientists with drug safety expertise to collaborate with OSE staff.

D. Develops a regulatory science program to support OSE by including pharmacoepidemiology, risk management, pharmacovigilance, and medication error detection and prevention.

E. Ensures OSE's informatic systems (eg, Adverse Event Reporting System, Phonetic Orthographic Computer Analysis) serve OSE’s needs through interaction with center and agency information technology staffs.

F. Provides coordination, development and assessment of policies, procedures, and best practices related to data and information system management within OSE, and data standards/.

G. Represents OSE in center and agency boards or workgroups that address business process improvements and information technology related to OSE’s mission.

3. REGULATORY AFFAIRS STAFF (DKKNO5).

A. Responsible for the coordination and implementation of regulatory policies by staff within OSE.

B. Coordinates the development and upkeep of guidances, MAPPs, and standard operating procedures.

C. Answers regulatory questions and manages the process for waivers of postmarketing safety reporting requirements and citizen petition responses.

D. Coordinates and leads OSE involvements on center- and agency-wide regulatory initiatives, such as development of safety regulations.

4. PROGRAM MANAGEMENT AND ANALYSIS STAFF (DKKNO8).

A. Provides leadership, direction, and planning for administrative and contract management programs for OSE.

B. Provides guidance and support services to the OSE on all aspects including administrative, budget and facilities management and provides service and support on human resource, personnel operations services and recruitment activities.

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

D. Provides representation for OSE on Center and Agency best practices boards associated with staff responsibilities.

5. PROJECT MANAGEMENT STAFF (DKKNO9).

A. Provides leadership, direction, planning, management and supervision of programs related to drug safety reviews and staff.

B. Provides management, tracking and facilitation of projects related to drug safety reviews within OSE.

C. Provides coordination, development and assessment of policies and procedures related to drug safety reviews, review templates and other best practices related to drug safety reviews within OSE.

D. Provides representation for OSE on Center best practices associated with staff responsibilities.

6. AUTHORITY AND EFFECTIVE DATE.

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

Staff Manual Guide 1261.5
Organizations and Functions
Effective Date: 12/10/2012

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
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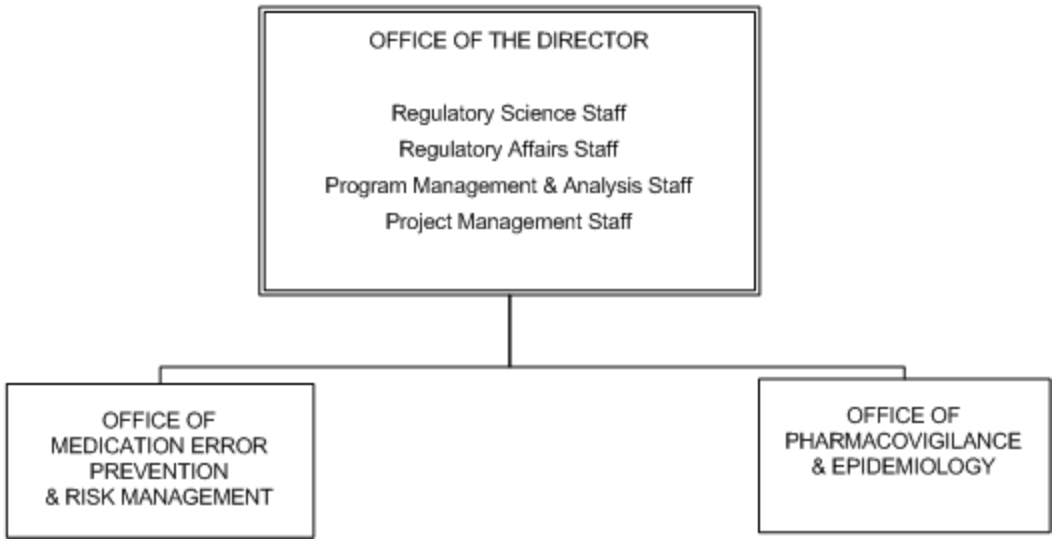

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology organization structure depicting all the organizational structures reporting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

OFFICE OF THE DIRECTOR:

- Regulatory Science Staff
- Regulatory Affairs Staff
- Program Management & Analysis Staff
- Project Management Staff
- OFFICE OF MEDICATION ERROR PREVENTION
- OFFICE OF PHARMACOVIGILANCE AND EPIDEMIOLOGY