SMG 1262.5

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 COMPLIANCE

OFFICE OF SCIENTIFIC INVESTIGATIONS

Effective Date: September 26, 2014

1. OFFICE OF SCIENTIFIC INVESTIGATIONS (DKKNDE).

A. Develops and implements patient focused, risk-based programs and policies for inspection, compliance, and enforcement of the following regulatory areas: nonclinical and clinical drug product studies, bioequivalence studies, human subject protections in clinical drug product studies, Postmarket Adverse Drug Experience (PADE), Risk Evaluation and Mitigation Strategies (REMS), and, Postmarketing Requirements (PMR), and Safety Labeling.

B. Develops and implements, with the Office of Medical Policy (OMP), the Office of Translational Science (OTS), and the Office of Regulatory Affairs (ORA), the Agency's Bioresearch Monitoring Program for Human Drugs under the applicable laws and regulations.

C. Develops and formalizes regulatory strategies and guidance including the Center for Drug Evaluation and Research (CDER) Manual of Policies and Procedures (MaPPs), Staff Guidance Manuals, and Compliance Program Guidance Manuals to promote compliance with Good Clinical Practice (GCP) in research, human subject protections, Good Laboratory Practices (GLP), Bioequivalence, PADE reporting, REMS, PMR, and Safety Labeling.

2. POLICY STAFF (DKKNDE1).

A. Develops patient-focused, risk-based compliance and enforcement policies, including review of warning letters and disqualifications for the Bioresearch Monitoring and Postmarketing programs.

B. Formalizes the regulatory strategy for the Office of Scientific Investigations (OSI’s) programs and is supplies expertise for coordination of regulatory actions with the Office of Chief Counsel and the Office of the Commissioner.

C. Provides regulatory counsel support for OSI regulatory actions and for and Good Laboratory Practice programs.

D. Develops and implements the enforcement programs for postmarketing study requirements.

3. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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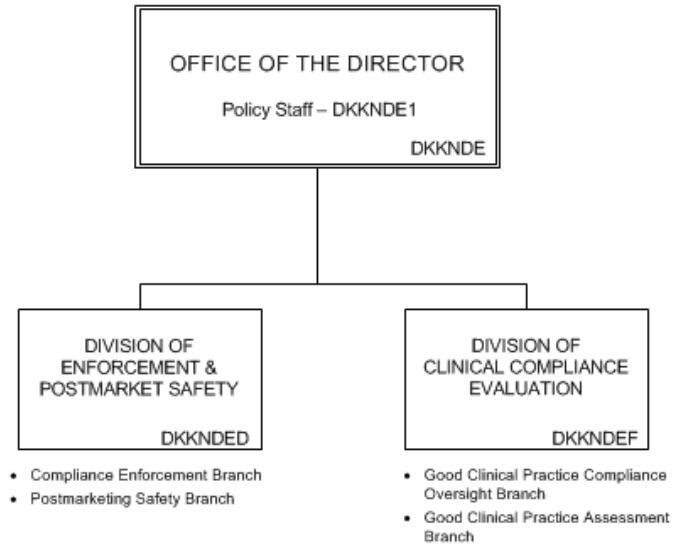

- Compliance Enforcement Branch
- Postmarketing Safety Branch

- Good Clinical Practice Compliance Oversight Branch
- Good Clinical Practice Assessment Branch

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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 Compliance, Office of Scientific Investigations organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNDE:

- Policy Staff – DKKNDE1

- DIVISION OF ENFORCEMENT AND POSTMARKET SAFETY – DKKNDED
  - Compliance Enforcement Branch – DKKNDED1
  - Postmarketing Safety Branch – DKKNDED2
- DIVISION OF CLINICAL COMPLIANCE EVALUATION – DKKNDEF
  - Good Clinical Practice Compliance Oversight Branch – DKKNDEF1
  - Good Clinical Practice Assessment Branch – DKKNDEF2