SMG 1268.6a

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 TRANSLATIONAL SCIENCES

OFFICE OF STUDY INTEGRITY AND SURVEILLANCE

Effective Date: September 26, 2014

1. OFFICE OF STUDY INTEGRITY AND SURVEILLANCE (DKKNGE).

A. Develops and implements programs and policies for inspection, compliance, and enforcement of the following regulatory areas: nonclinical studies, bioequivalence studies, and human subject protections in clinical drug product studies.

B. Develops and implements, with the Center for Drug Evaluation and Research (CDER) Office of Medical Policy (OMP), the CDER Office of Compliance (CDER OC), and the Office of Regulatory Affairs (ORA), the Agency's Bioresearch Monitoring Program for Human Drugs under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Food and Drug Amendments Act, other Federal statutes, and applicable regulations.

C. Develops and formalizes regulatory strategies and guidance including CDER's 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, Adverse Drug Experience, Risk Evaluation and Mitigation Strategies, and Safety.

2. AUTHORITY AND EFFECTIVE DATE.

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

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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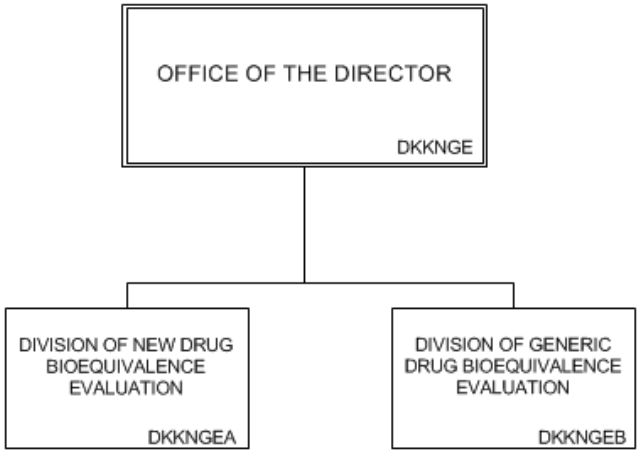

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Translational Sciences, Office of Study Integrity and Surveillance organization structure depicting all the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

OFFICE OF THE DIRECTOR – DKKNGE:

- Division of New Drug Bioequivalence Evaluation - DKKNGEA

- Division of Generic Drug Bioequivalence Evaluation - DKKNGEB