SMG 1268.62

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

DIVISION OF GENERIC DRUG BIOEQUIVALENCE EVALUATION

Effective Date: September 26, 2014

1. DIVISION OF GENERIC DRUG BIOEQUIVALENCE EVALUATION (DKKNGEB).

A. Designs, operates, directs and participates in inspections in collaboration with Office of Regulatory Affairs (ORA) to verify the quality, integrity, and human subject protections (rights, safety and welfare) of pharmacokinetic, pharmacodynamic, and bioavailablity studies, and provides assessments of the acceptability of study data to Center for Drug Evaluation and Research (CDER) Office of Generic Drugs (OGD).

B. Reviews establishment inspection reports (EIRs) from ORA to evaluate bioequivalence firms (both clinical and analytical laboratories) that are involved in pharmacokinetic and pharmacodynamic studies submitted in support of investigational new drug applications (INDs), and Abbreviated New Drug Applications (ANDAs).

C. Evaluates compliance issues to make data acceptability recommendations and works with CDER Office of Complaice (OC) to determine if follow-up actions, such as issuance of warning letters or other regulatory actions, are warranted.

E. Evaluates complaints, citizen petitions, and issues for-cause/directed inspection assignments.

D. Designs and implements the bioanalytical lab surveillance program.

E. Monitors and responds to significant issues concerning analytical aspects of generic drug development.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division 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
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF TRANSLATIONAL SCIENCES
OFFICE OF STUDY INTEGRITY AND SURVEILLANCE
DIVISION OF GENERIC DRUG BIOEQUIVALENCE EVALUATION

OFFICE OF THE DIRECTOR

DKKNGEB

STAFF MANUAL GUIDE 1268.62
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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, Division of Generic Drug Bioequivalence Evaluation organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR - DKKNGEB