SMG 1262.51

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

DIVISION OF BIOEQUIVALENCE AND GOOD LABORATORY PRACTICE COMPLIANCE

Effective Date: 07/08/2011

1. DIVISION OF BIOEQUIVALENCE AND GOOD LABORATORY PRACTICE COMPLIANCE (DKKNDEA)

A. Designs and operates surveillance and compliance programs in the areas of nonclinical bioequivalence studies for new and generic drugs

B. Assigns, directs and coordinates onsite inspections in collaboration with the Agency's field organization in order to monitor facilities conducting non-clinical, bioequivalence, and bioavailability (pharmacokinetics, and pharmacodynamic) studies and the supporting analytical laboratories

C. Evaluates inspectional reports, develops and issues correspondence to the inspected party, and initiates administrative and regulatory corrective measures as necessary

D. Consults with CDER's review divisions to identify sites for inspection relating to bioequivalence, bioavailability, and nonclinical (i.e., animal) studies (in vitro and in vivo) used to support INDs, ANDAs, or NDAs. These studies include pharmacokinetic, pharmacodynamic, toxicokinetic and bioequivalence studies

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

2. BIOEQUIVALENCE BRANCH (DKKNDEA2)

A. Designs, operates, directs and participates in inspections to verify the quality and integrity of study data of pharmacokinetic, pharmacodynamic, toxicokinetic and bioequivalence studies (e.g., studies that link the formulation used during drug development with the current to-be-marketed formula (NDAs) or evaluation of generic copies of innovator drug products (ANDAs), and provides assessments of the acceptability of study data to CDER review divisions

B. Reviews establishment inspection reports (EIRs) from FDA field offices to evaluate:

C. Bioequivalence facilities (both clinical and analytical laboratories) that are involved in pharmacokinetic and pharmacodynamic studies submitted in support of NDAs and ANDAs

D. Significant compliance issues in order to make data acceptability recommendations and to determine if follow-up actions, such as issuance of warning letters or other regulatory actions, are necessary

3. GOOD LABORATORY PRACTICE BRANCH (DKKNDEA1)

A. Designs, operates, directs and participates in inspections of nonclinical (i.e., animal) safety studies (in vitro and in vivo) submitted in support of INDs or NDAs, to verify the quality and integrity of study data and provides assessments of the acceptability of study data to CDER review divisions

B. Reviews establishment inspection reports (EIRs) from FDA field offices to evaluate nonclinical laboratories that perform preclinical safety studies

4. AUTHORITY AND EFFECTIVE DATE

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/20/2011	N/a	CDER/OM	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

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OFFICE OF THE DIRECTOR

Good Laboratory Practice Branch

Bioequivalence Branch

Staff Manual Guide 1262.51
Organizations and Functions
Effective Date: July 8, 2011

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, Division of Bioequivalence and Good Laboratory Practice Compliance organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- Good Laboratory Practice Branch
- Bioequivalence Branch