SMG 1268.61

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 NEW DRUG BIOEQUIVALENCE EVALUATION

Effective Date: September 26, 2014

1. DIVISION OF NEW DRUG BIOEQUIVALENCE EVALUATION (DKKNGEA).

A. Designs, operates, directs and participates in inspections in collaboration with ORA to verify the quality, integrity, and human subject protections (rights, safety and welfare) of pharmacokinetic, pharmacodynamic, and bioequivalence studies, and provides assessments of the acceptability of study data to CDER Office of New Drugs (OND).

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), Abbreviated New Drug Applications (NDAs), and biological license applications (BLAs).

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

D. Designs, operates, directs and participates in inspections of nonclinical studies submitted in support of INDs, NDAs, or BLAs to verify the quality and integrity of study data and provides assessments of the acceptability of study data to CDER review divisions.

E. Reviews EIRs from FDA field office inspections of nonclinical laboratories for inspections that OSIS did not participate in, to evaluate the quality of work performed by the laboratories and recommend follow-up regulatory actions, as warranted.

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

G. Works with foreign regulatory agencies, including the European Medicines Agency (EMA) on information sharing and inspectional collaborations.

H. Monitors and responds to significant issues concerning analytical aspects of new 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.

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OFFICE OF THE DIRECTOR

DKKNGEA

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

OFFICE OF THE DIRECTOR - DKKNGEA