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FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Translational Sciences

Office of Study Integrity & Surveillance

Division of New Drug Study Integrity

Effective Date: September 25, 2019

1. Division of New Drug Study Integrity (DCDJDA).

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 bioequivalence studies, and provides assessments of the acceptability of study data to Center for Drug Evaluation and Research (CDER), Office of New Drugs.

B. Reviews establishment inspection reports 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 (ANDAs), and biological license applications (BLAs).

C. Evaluates compliance issues to make data acceptability recommendations to OND and works with CDER Office of Compliance 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, ANDAs, 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 establishment inspection reports from Food and Drug Administration field office inspections of nonclinical laboratories for inspections that the Office of

Study Integrity and Surveillance 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 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 the Division of New Drug Study Integrity were approved by the Secretary of the Health and Human Services on September 25, 2019.

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Translational Science, Office of Study Integrity & Surveillance, Division of New Drug Study Integrity organizational structures depicting all the organizational structures reporting to the Director.

Division of New Drug Study Integrity (DCDJDA).

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