

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 and Surveillance

Division of Generic Drug Study Integrity

Effective Date: September 25, 2019

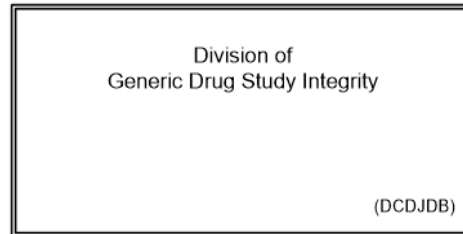
1. Division of Generic Drug Study Integrity (DCDJDB).

- 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 bioavailability studies, and provides assessments of the acceptability of study data to Center for Drug Evaluation and Research (CDER), Office of Generic 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, and Abbreviated New Drug Applications.
- C. Evaluates compliance issues to make data acceptability recommendations 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.
- 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 the Division of Generic Drug Study Integrity were approved by the Secretary of Health and Human Services on September 25, 2019.

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Staff Manual Guide 1268.62
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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 Generic Drug Study Integrity organizational structures depicting all the organizational structures reporting to the Director.

Division of Generic Drug Study Integrity (DCDJDB).