

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 Compliance

Office of Science Investigations

Division of Enforcement and Postmarket Safety

Effective Date: December 14, 2018

1. Division of Enforcement and Postmarket Safety (DCDFCC).

- A. Develops and implements compliance and enforcement programs, including the review of significantly violative inspections that may result in compliance or enforcement action that were conducted under the direction of Office of Medical Policy, Office of Translational Science or Office of Scientific Investigation inspection programs.
- B. Develops patient-focused, risk-based compliance and enforcement actions, including warning letters and disqualifications for the Bioresearch Monitoring and Postmarketing programs.
- C. Provides oversight of the Food and Drug Administration's (FDA) compliance actions related to the FDA requirements for Risk Evaluation and Mitigation Strategies, Postmarket Adverse Drug Experience reporting, and Safety Labeling by monitoring sponsors and manufacturers for compliance with Risk Evaluation and Mitigation Strategies, Postmarket Adverse Drug Experience and Safety Labeling commitments and initiates regulatory actions where warranted.

2. Compliance Enforcement Branch (DCDFCC1).

- A. Reviews all significantly violative inspections that may result in compliance or enforcement action relating to inspections of clinical investigators, sponsors, monitors, contract research organizations, nonclinical and bioanalytical labs, and clinical sites conducting bioequivalence studies, and evaluates the evidence and

risks and executes steps necessary to resolve the issue(s), such as regulatory actions, including warning letters, disqualifications, restrictions, etc.

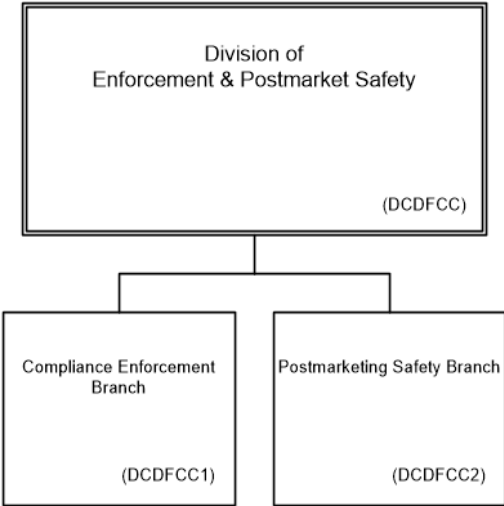
3. Postmarketing Safety Branch (DCDFCC2).

- A. Assigns, directs and coordinates onsite inspections in collaboration with Office of Regulatory Affairs in order to monitor adherence to regulations and statutes governing Postmarket Adverse Drug Experience reporting requirements and Risk Evaluation and Mitigation Strategies.
- B. Reviews all significantly violative Postmarket Adverse Drug Experience and Risk Evaluation and Mitigation Strategies inspections that may result in compliance or enforcement action, and evaluates the evidence and risks and executes steps, such as regulatory actions, necessary to resolve the issue(s).

4. Authority and Effective Date.

The functional statements for the Division of Enforcement and Postmarket Safety were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Scientific Investigations
Division of Enforcement & Postmarket Safety**



Staff Manual Guide 1262.54
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Scientific Investigations, Division of Enforcement & Postmarket Safety organization structure depicting all the organizational structures reporting to the Director.

Division of Enforcement & Postmarket Safety (DCDFCC)

These organizations report to the Division of Enforcement & Postmarket Safety:

Compliance Enforcement Branch (DCDFCC1)

Postmarketing Safety Branch (DCDFCC2)