

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 ENFORCEMENT AND POSTMARKET SAFETY

Effective Date: September 26, 2014

1. DIVISION OF ENFORCEMENT AND POSTMARKET SAFETY (DKKNDED).

- 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 (OSI's) 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's) 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 (DKKNDED1).

- 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.

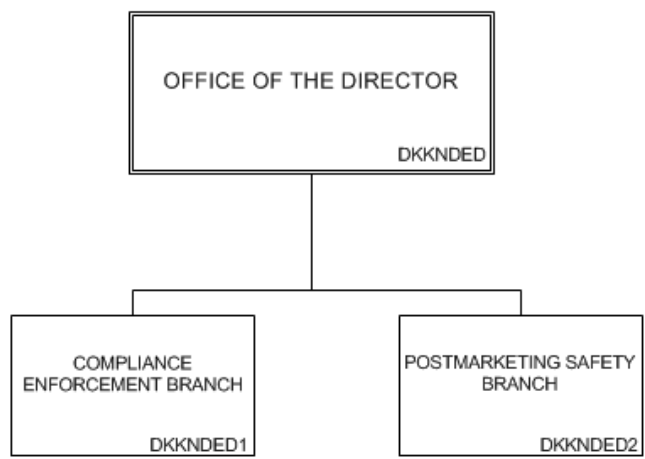
3. POSTMARKETING SAFETY BRANCH (DKKNDED2).

- 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 this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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ORGANIZATIONS AND FUNCTIONS
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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 Compliance, Office of Scientific Investigations, Division of Enforcement and Postmarket Safety organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNDED:

- Compliance Enforcement Branch – DKKNDED1
- Postmarketing Safety Branch – DKKNDED2