SMG 1262.5

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

Effective Date: December 14, 2018

1. Office of Scientific Investigations (DCDFC).

A. Develops and implements patient focused, risk-based programs and policies for inspection, compliance, and enforcement of the following regulatory areas: nonclinical and clinical drug product studies, bioequivalence studies, human subject protections in clinical drug product studies, Postmarket Adverse Drug Experience (PADE), Risk Evaluation and Mitigation Strategies (REMS), and, Postmarketing Requirements (PMR), and Safety Labeling.

B. Develops and implements, with the Office of Medical Policy, the Office of Translational Science, and the Office of Regulatory Affairs, the Agency's Bioresearch Monitoring Program for Human Drugs under the applicable laws and regulations.

C. Develops and formalizes regulatory strategies and guidance including the Center for Drug Evaluation and Research Manual of Policies and Procedures, Staff Guidance Manuals, and Compliance Program Guidance Manuals to promote compliance with Good Clinical Practice in research, human subject protections, Good Laboratory Practices, Bioequivalence, PADE reporting, REMS, PMR, and Safety Labeling.

2. Policy Staff (DCDFC1).

A. Develops patient-focused, risk-based compliance and enforcement policies, including review of warning letters and disqualifications for the Bioresearch Monitoring and Postmarketing programs.

B. Formalizes the regulatory strategy for the Office of Scientific Investigations (OSI's) programs and is supplies expertise for coordination of regulatory actions with the Office of Chief Counsel and the Office of the Commissioner.

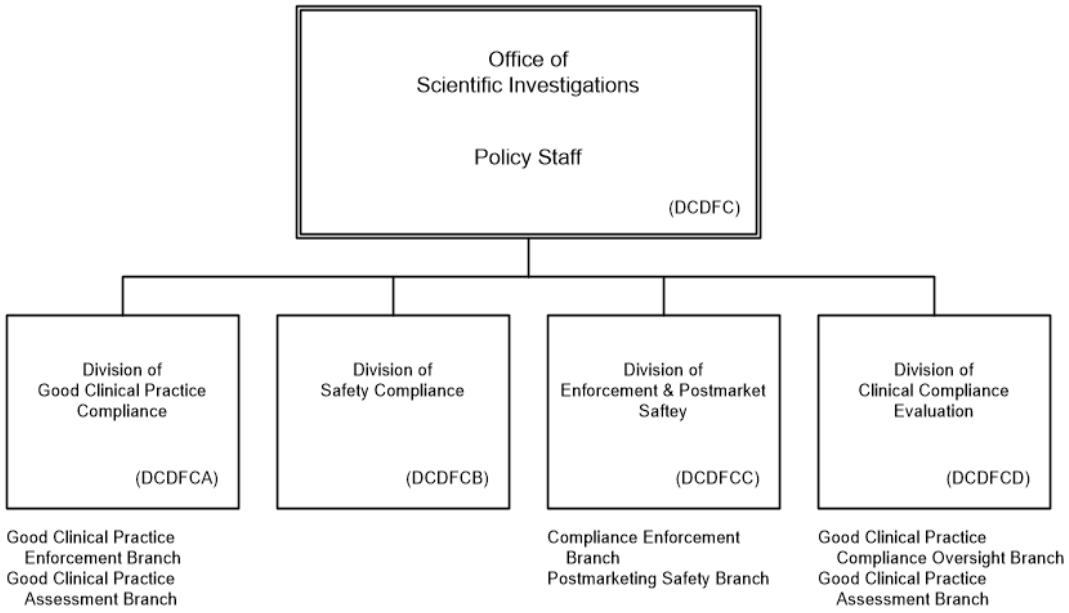
C. Provides regulatory counsel support for OSI regulatory actions and for and Good Laboratory Practice programs.

D. Develops and implements the enforcement programs for postmarketing study requirements.

3. Authority and Effective Date.

The functional statements for the Office of Scientific Investigations 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



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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 Compliance, Office of Scientific Investigations organization structure depicting all the organizational structures reporting to the Director.

Office of Scientific Investigations (DCDFC)

These organizations report to the Office of Scientific Investigations:
Policy Staff
Division of Good Clinical Practice Compliance (DCDFCA)
Division of Safety Compliance (DCDFCB)
Division of Enforcement & Postmarket Safety (DCDFCC)
Division of Clinical Compliance Evaluation (DCDFCD)

These organizations report to the Division of Good Clinical Practice Compliance:
Good Clinical Practice Enforcement Branch (DCDFCA1)
Good Clinical Practice Assessment Branch (DCDFCA2)

These organizations report to the Division of Enforcement & Postmarket Safety:
Compliance Enforcement Branch (DCDFCC1)
Postmarketing Safety Branch (DCDFCC2)

These organizations report to the Division of Clinical Compliance Evaluation:
Good Clinical Practice Compliance Oversight Branch (DCDFCD1)
Good Clinical Practice Assessment Branch (DCDFCD2)

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