

**SMG 1262.1**

**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**

Effective Date: December 14, 2018

**1. Office of Compliance (DCDF).**

- A. Plans, develops, and directs compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.
- B. Advises the Center Director and other officials on Food and Drug Administration's regulatory and enforcement responsibilities and possible risks associated with human drugs.
- C. Implements programs and projects to identify, assess, and prioritize the public health significance and patient risk associated with drug quality and safety concerns presented throughout the drug lifecycle.
- D. Leads and oversees the development of human drug enforcement and compliance policy and standards.
- E. Develops and guides compliance strategies and enforcement actions, and ensures uniform interpretation of standards.
- F. Oversees the planning and development of compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.
- G. Executes high-level decisions, monitors performance, and directs strategies and operations of component offices to ensure compliance and enforcement decisions and policies are patient-focused and risk-based.

H. Designs and develops internal procedures and processes to support work quality, and oversight of implementation, monitoring, and continual improvement of the quality system.

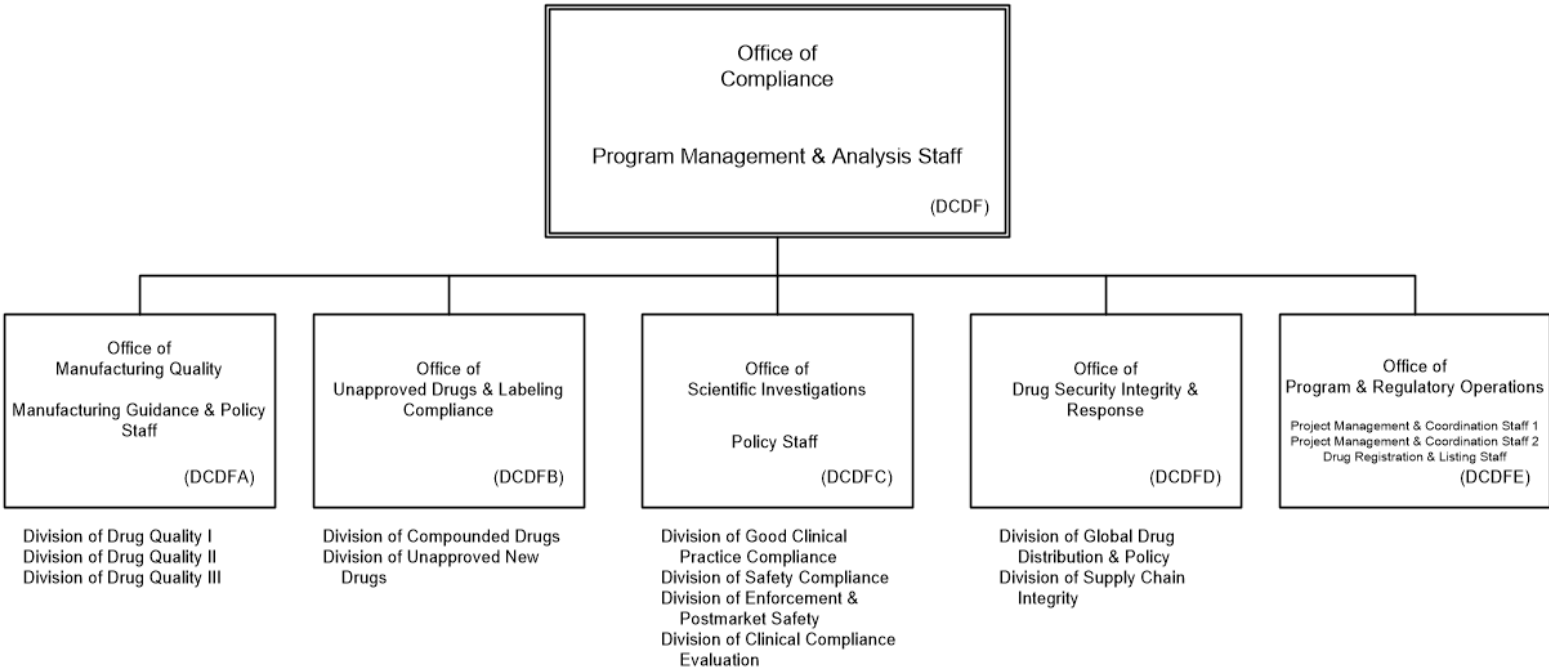
**2. Program Management and Analysis Staff (DCDF1).**

A. Provides leadership, guidance and support services to the Office of Compliance on all aspects of administrative, budget, contracts and provides service and support on human resource, personnel operations services and recruitment activities.

**3. Authority and Effective Date.**

The functional statements for the Office of Compliance 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**



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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 organization structure depicting all the organizational structures reporting to the Director.

#### Office of Compliance (DCDF)

These organizations report to the Office of Compliance:

- Program Management & Analysis Staff
- Office of Manufacturing Quality (DCDFA)
- Office of Unapproved Drugs & Labeling Compliance (DCDFB)
- Office of Scientific Investigations (DCDFC)
- Office of Drug Security Integrity & Response (DCDFD)

These organizations report to the Office of Manufacturing Quality:

- Manufacturing Guidance & Policy Staff
- Division of Drug Quality I
- Division of Drug Quality II
- Division of Drug Quality III

These organizations report to the Office of Unapproved Drugs & Labeling Compliance:

- Division of Compounded Drugs
- Division of Unapproved New Drugs

These organizations report to the Office of Scientific Investigations:

- Policy Staff
- Division of Good Clinical Practice Compliance
- Division of Safety Compliance
- Division of Enforcement & Postmarket Safety
- Division of Clinical Compliance Evaluation

These organizations report to the Office of Drug Security Integrity & Response:

- Division of Global Drug Distribution & Policy
- Division of Supply Chain Integrity