

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

Office of Regulatory Programs

Effective Date: December 14, 2018

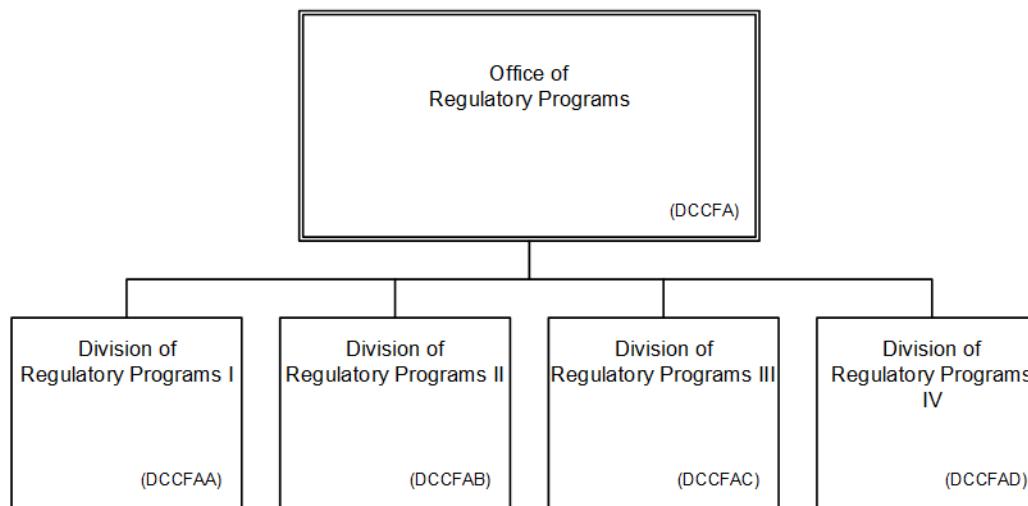
1. Office of Regulatory Programs (DCCFA).

- A. Responsible for managing the various regulatory programs and providing high-level programmatic support for device specific offices engaging in total product life cycle review of devices.
- B. Provides programmatic expertise, develops policy interpretations and analysis, provides review processes and tools, and addresses novel or complex policy exceptions for purposes of ensuring consistency among device specific offices.
- C. Provides logistical support on document control, automated systems, quality assurance, and corrections to device submissions for device specific offices.
- D. Ensures the proper application of Food and Drug Administration (FDA) and Center for Devices and Radiological Health (CDRH) policy to jurisdictional decisions including 513(g) reviews device determinations and custom devices.

2. Authority and Effective Date.

The functional statements for the Office of Regulatory Programs 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 Devices and Radiological Health
Office of Product Evaluation and Quality
Office of Regulatory Programs**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation & Quality, Office of Regulatory Programs organization structure depicting all the organizational structures reporting to the Director.

Office of Regulatory Programs (DCCFA)

- Division of Regulatory Programs I (DCCFAA)
- Division of Regulatory Programs II (DCCFAB)
- Division of Regulatory Programs III (DCCFAC)
- Division of Regulatory Programs IV (DCCFAD)