SMG 1258.13

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

Division of Regulatory Programs III

Effective Date: January 6, 2022

1. Division of Regulatory Programs III (DCCFAC).

A. Responsible for developing, interpreting and implementing policy and process for programs related to assuring the continued safety of marketed devices.

B. Provides programmatic expertise for Recalls, Allegations, Device Shortage Assessments, Medical Device Report (MDR) reviews, as well as potential enforcement actions associated with these programs.

C. Develops tools for purposes of identifying and assessing product safety issues and targeting optimal use of resources.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Programs III were approved by the Deputy Secretary of Health and Human Services on October 22, 2021 and effective on January 6, 2022.

Department of Health and Human Services
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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, Division of Regulatory Programs III organization structure depicting all the organizational structures reporting to the Director.

Division of Regulatory Programs III (DCCFAC)