SMG 1258.11

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 Program I

Effective Date: December 14, 2018

1. Division of Regulatory Programs I (DCCFAA).

A. Responsible for developing, interpreting and implementing programmatic support and driving policy and process development for programs related to management of regulatory submissions.

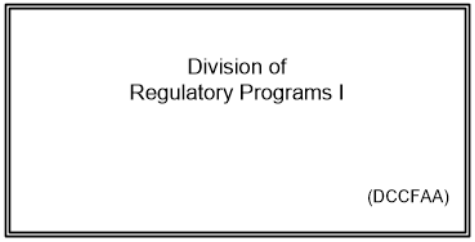
B. Provides programmatic expertise for policy interpretation, historic regulatory decisions and analogs, and answers on novel or complex exceptions regarding submission policy including submissions such as 510(k)s, PMAs, HDE, DeNovo, Presubmissions, labeling compliance (EIR classification and/or potential enforcement action), Custom Device, and Medical Device Tracking.

C. Responsible for ensuring proper application of the Center for Devices and Radiological Health (CDRH) and the Food and Drug Administration (FDA) policy to jurisdictional decisions including combination products, 513(g) reviews, device determinations and custom devices.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Programs I 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
Division of Regulatory Programs I



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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 and Quality, Office of Regulatory Programs, Division of Regulatory Programs I organization structure depicting all the organizational structures reporting to the Director.

Division of Regulatory Programs I (DCCFAA)

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