SMG 1258.21

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 Clinical Evidence and Analysis

Division of Clinical Evidence and Analysis I

Effective Date: December 14, 2018

1. Division of Clinical Evidence and Analysis I (DCCFBA).

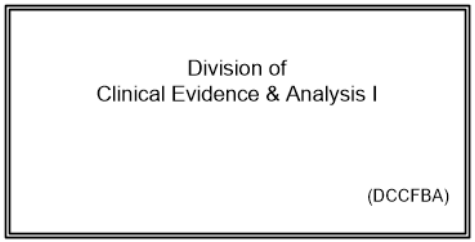
A. Responsible for developing policy and providing program support across clinical evidence areas including clinical investigations, bioresearch compliance, human subject protection, clinical and evidence synthesis, analysis, and data infrastructure for Device Specific Offices engaged in total product lifecycle review of devices.

B. Responsible for conducting outreach and collaboration with hospitals and other external stakeholders.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Evidence and Analysis 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 Clinical Evidence and Analysis 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 Clinical Evidence and Analysis, Division of Clinical Evidence and Analysis I organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Evidence & Analysis I (DCCFBA)