

SMG 1258.22

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 II

Effective Date: December 14, 2018

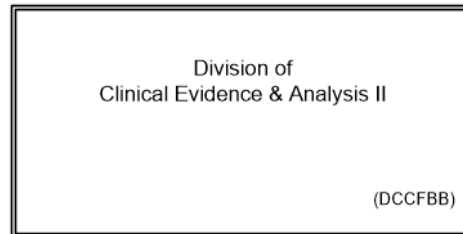
1. Division of Clinical Evidence and Analysis II (DCCFBA).

- A. Responsible for supporting device reviews that require expert biostatistics analysis.
- B. Responsible for covering analysis in both therapeutic biostatistics and diagnostic biostatistics.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Evidence and Analysis II were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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

Division of Clinical Evidence & Analysis II (DCCFBB)