

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drugs Evaluation and Research

Office of Generic Drugs

Office of Regulatory Operations

Division of Filing Review

Effective Date: December 14, 2018

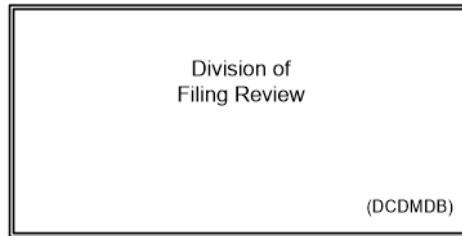
1. Division of Filing Review (DCDMDB).

- A. Reviews newly submitted Abbreviated New Drug Applications to determine if they are “sufficiently complete” to be received.
- B. Monitors and issues Refusal to Receive letters.
- C. Provides evaluation of patent and exclusivity issues.

2. Authority and Effective Date.

The functional statements for the Division of Filing Review 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
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Division Filing Review**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Regulatory Operations, Division of Filing Review organizational structures depicting all the organizational structures reporting to the Director:

Division of Filing Review (DCDMDB)