

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: October 9, 2020

1. Division of Filing Review (DCDMDB).

- A. Reviews newly submitted Abbreviated New Drug Applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs including complex products 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.
- D. Determines the appropriate prioritization of applications received for medically necessary drug products.
- E. Assesses requests for changes to approved drug products.

2. Authority and Effective Date.

The functional statements for the Division of Filing Review were approved by the Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020.

**Department of Health and Human Services
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Division of
Filing Review

(DCDMDB)

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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, organization structure depicting all the organizational structures reporting to the Director:

Division of Filing Review (DCDMDB)