

**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 Labeling Review**

Effective Date: December 14, 2018

**1. Division of Labeling Review (DCDMDA).**

- A. Reviews and approves all aspects of labeling submissions for Abbreviated New Drug Applications (ANDAs), coordinating and consulting with the new drug divisions when necessary.
- B. Monitors New Drug Applications (NDA) labeling, including patent and exclusivity status, to advise generic drug applicants of correct model labeling and to prepare and update labeling guidance's.

**2. Authority and Effective Date.**

The functional statements for the Division of Labeling 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  
Center for Drug Evaluation and Research  
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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 Labeling Review organizational structures depicting all the organizational structures reporting to the Director:

Division of Labeling Review (DCDMDA)