

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 Project Management

Effective Date: December 14, 2018

1. Division of Project Management (DCDMDC).

- A. Provides for the management of the review processes associated with the Abbreviated New Drug Applications (ANDAs) across all review disciplines, by planning, organizing, prioritizing, and assigning ANDA review work.
- B. Monitors and controls review resources and outcomes to assure achievement of individual, team, discipline and Office review goals.
- C. Monitors the compliance evaluation processes for all facilities associated with an ANDA.
- D. Continuously optimizes the allocation of review resources to improve review efficiency.

2. Authority and Effective Date.

The functional statements for the Division of Project Management were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
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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 Project Management organizational structures depicting all the organizational structures reporting to the Director:

Division of Project Management (DCDMDC)