

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: October 9, 2020


1. Division of Project Management (DCDMDC).

- A. Provides management of the review processes associated with the Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs including complex products 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. Optimizes the allocation of review resources to improve review efficiency.
- D. Serves as the Food and Drug Administration lead for communications regarding drug application status inquiries from applicants.
- E. Compiles drug product deficiencies from the assessment teams into regulatory compliant Complete Response Letter action packages.

2. Authority and Effective Date.

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

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Division of
Project Management

(DCDMDC)

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

Division of Project Management (DCDMDC)