

SMG 1355.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Tobacco Products

Office of Science

Division of Regulatory Project Management

Effective: January 6, 2022

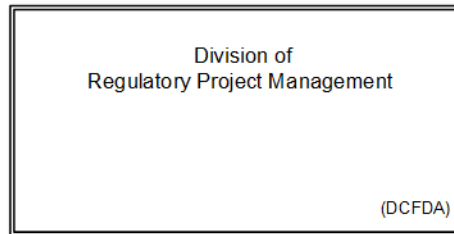
1. Division of Regulatory Project Management (DCFDA).

- A. Directs the tobacco product review process from initial submission to the time of regulatory action.
- B. Serves as the regulatory expert and primary point of contact for communications with regulated entities including industry and researchers related to product submissions.
- C. Develops and implements policies and procedures governing the submission and review of applications and other regulatory submissions including substantial equivalence, pre-market tobacco applications, and modified risk tobacco product applications.

2. Authority and Effective Date.

The functional statements for this Division were approved by the Deputy Secretary of Health and Human Services on October 22, 2021, and effective on January 6, 2022.

**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 Tobacco Products, Office of Science, Division of Regulatory Project Management organization structure depicting all the organizational structures reporting to the Division Director.

Division of Regulatory Project Management (DCFDA)