SMG 1355.3

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 Science Informatics

Effective: January 6, 2022

1. **Division of Regulatory Science Informatics (DCFDB).**

   A. Identifies advocates, and coordinates the identification, development, and management of tools and systems to support the regulatory science evaluation and approval of tobacco products.

   B. Leads information management activities and promotes efficient and informative data analysis methods to support the review and regulation of tobacco products for the Office of Science (OS).

   C. Provides IT leadership, advocacy, direction, coordination and tracking for specific IT projects associated with the improvement of Center for Tobacco Products (CTP) regulatory informatics on behalf of OS.

   D. Provides leadership, direction, policy development and coordination on strategic scientific computing plans and their implementation.

   E. Develops support and communication activities to ensure timely service and information sharing to both internal and external OS stakeholders.

   F. Develops electronic submission and data standards and associated regulatory guidance and process and tools to maximize efficiency and consistency of regulatory and scientific reviews.

   G. Develops requirements for information management systems and maintain them to support the full range of regulatory science projects, including preparation of reports for management use.

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
Food and Drug Administration
Center for Tobacco Products
Office of Science
Division of Regulatory Science Informatics

Division of
Regulatory Project Management

(DCFDB)

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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 Science Informatics organization structure depicting all the organizational structures reporting to the Division Director.

Division of Regulatory Science Informatics (DCFDB)