SMG 1258.90

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

Office of Health Technology VII

Effective Date: May 13, 2024

1. Office of Health Technology VII (DCCFI).

A. Responsible for executing end-to-end device review programs and activities; this includes premarket, compliance and quality, and post-market surveillance reviews.

B. Works closely with other offices on classification and reclassification activities, and the development of guidance documents.

C. Provides initial support for questions related to regulatory programs in response to specific requests from medical device and health technology industries, trade associations, other Federal agencies, other countries, State agencies, and the general public.

D. Directs review of files, including applications for pre-market approval (PMAs), premarket notification of intent to market a product, product development protocols (PDPs), applications for investigational device exemptions (IDEs), De Novo, 513(g)s, inspection classification, allegations, recalls, Custom Device Reports, MDRs, import alerts, and information from other government agencies, and other product safety and compliance information.

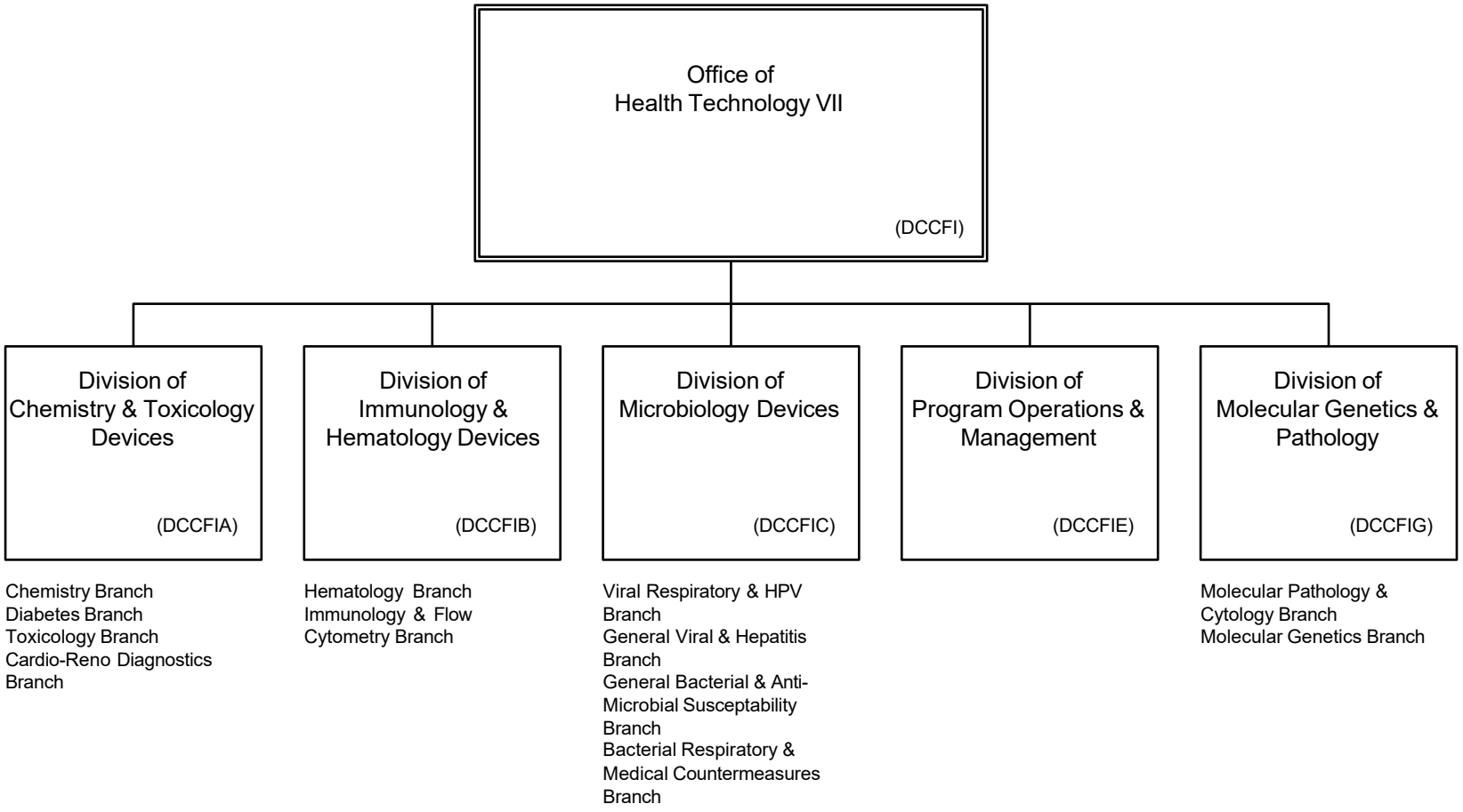
E. Maintains and analyzes device-related compliance data and uses this data to support Office and Center-level activities, makes determinations on enforcement actions, and determine follow-up activities.

F. Participates in the development of national and international consensus standards, and voluntary guidelines through interaction with appropriate national and international standards committees.

2. Authority and Effective Date.

The functional statements for the Office of Health Technology VII were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Health Technology VII



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation and Quality, Office of Health Technology VII organization structure depicting all the organizational structures reporting to the Director:

Division of Chemistry and Toxicology Devices (DCCFIA)

Division of Immunology and Hematology Devices (DCCFIB)

Division of Microbiology Devices (DCCFIC)

Division of Program Operations and Management (DCCFIE)

Division of Molecular Genetics and Pathology (DCCFIG)