

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 Strategic Partnerships and Technology Innovation

Digital Health Center of Excellence

Division of Digital Health Technology Assessment

Effective: August 8, 2023

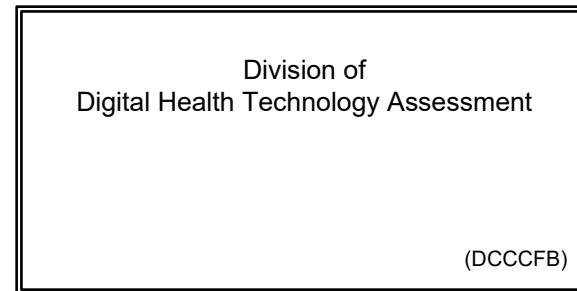
1. Division of Digital Health Technology Assessment (DCCCFB).

- A. Provides leadership and serves as an expert resource for software and digital health technology and innovation assessments by providing advice and consultation to the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), the Department of Health and Human Services and other U.S. Government entities.
- B. Leads the FDA in the development and implementation of digital health technology regulatory paradigms and standards, promoting novel approaches to accelerate access.

2. Authority and Effective Date.

The functional statements for the Division of Digital Health Technology Assessment were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

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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 Scientific Programs and Technology Innovation, Digital Health Center of Excellence, Division of Digital Health Technology Assessment organization structure depicting all the organizational structures reporting to the Director:

Division of Digital Health Technology Assessment (DCCCFB)