

SMG 1251.22a

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

Division of Digital Health

Effective Date: December 14, 2018

1. Division of Digital Health (DCCCB).

- A. Provides leadership and strategic direction on all software and digital health topics for the Center.
- B. Provides Center oversight and leadership in the development, review, and implementation of regulations, policies, procedures and guidances related to software and digital health topics, and in the development of new legislation.
- C. Serves as the Center's focal point on regulatory issues providing advice and assistance on such matters as scope, applicability and meaning of the Federal Food, Drug, and Cosmetic Act law, regulations, and policies affecting software and digital health.
- D. Oversees, directs, coordinates and monitors consistent application of scientific, technical and policy, procedures and activities for all digital health and software topics for the Center.
- E. Develops and establishes strategic partnerships with industry groups, health professionals, consumers, and other national and international government agencies for developing and disseminating educational and programmatic information.
- F. Serves as an expert resource for software and digital health scientific, technical and policy matters by providing advice and consultation to the Center for Devices and Radiological Health (CDRH) Center Director, CDRH offices, and Food and Drug Administration (FDA) officials including the Office of the Commissioner.

G. Addresses cross-cutting digital health technical, human capital and regulatory policy needs of the Center and external stakeholders.

2. Authority and Effective Date.

The functional statements for the Division of Digital were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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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 Strategic Partnerships and Technology Innovation, Division of Digital Health organization structure depicting all the organizational structures reporting to the Director.

Division of Digital Health (DCCCB)