



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST) has modified its organizational structure.

DATES: These new organizations' structures were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

FOR FURTHER INFORMATION CONTACT: Denise Huttenlocker, Associate Director for Management, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, 10903 New Hampshire Ave, Silver Spring, MD 20993, 240-743-1760.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect Food and Drug Administration's reorganization of CDRH, OST.

This reorganization changed the OST organizational structure from an office with three divisions to an office with five suboffices each with their own divisions. The previous divisions were: the Division of All Hazards Response, Science and Strategic Partnerships, the Division of

Digital Health, and the Division of Technology and Data Services. The OST will elevate the programs performed by these former divisions to a super office structure whereby these divisions are abolished, and their functions and resources are realigned across five new OST suboffices.

DCCC. ORGANIZATION. The Office of Office of Strategic Partnerships and Technology Innovation is headed by the Director of Strategic Partnerships and Technology Innovation and includes the following organizational units:

Office of Readiness and Response

Division of All Hazards Preparedness and Response

Division of Standards and Conformity Assessment

Division of Medical Device Cybersecurity

Office of Equity and Innovative Development

Division of Patient-Centered Development

Division of Health Equity

Division of Partnerships and Innovation

Digital Health Center of Excellence

Division of Digital Health Policy

Division of Digital Health Technology Assessment

Division of Digital Health Outreach

Office of Technology and Data Services

Division of Business Transformation Delivery

Division of Technology Services

Division of Data Services

Office of Supply Chain Resilience

Division of Prevention, Innovation, and Resilience

Division of Shortage Assessment and Product Authentication

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at:

<http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>

(Authority: 44 U.S.C. 3101.)

Dated: August 9, 2023.

Xavier Becerra,

Secretary of Health and Human Services.

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