



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's (FDA), Center for Devices and Radiological Health's (CDRH), Office of Product Evaluation and Quality (OPEQ) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on December 21, 2023, and it became effective on January 22, 2024.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, Food and Drug Administration, 4041 Powder Mill Rd., Beltsville, MD, 20705-4304, 301-796-3843.

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 the reorganization of the CDRH OCE.

The reorganization of OPEQ impacted the OPEQ's Office of Clinical Evidence and Analysis (OCEA) and the OPEQ's Office of Health Technology IV (OHT IV). OCEA established the Division of Clinical Evidence and Analysis IV and the Division of Clinical Evidence and Analysis V. OHT IV established the Division of Health Technology IV C.

DCCFB. ORGANIZATION. CDRH's OPEQ OCEA is headed by the Director, and includes the following:

Office of Clinical Evidence and Analysis (DCCFB)

Division of Clinical Evidence and Analysis I (DCCFBA)

Division of Clinical Evidence and Analysis II (DCCFBB)

Division of Clinical Evidence and Analysis III (DCCFBC)

Division of Clinical Evidence and Analysis IV (DCCFBD)

Division of Clinical Evidence and Analysis V (DCCFBE)

DCCFF. ORGANIZATION. CDRH's OPEQ OHT IV is headed by the Director, and includes the following:

Office of Health Technology IV (DCCFF)

Division of Health Technology IV A (DCCFFA)

Division of Health Technology IV B (DCCFFB)

Division of Health Technology IV C (DCCFFC)

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:

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

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

Xavier Becerra,

Secretary

Department of Health and Human Services.

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