

The reorganization retitled OCE as the Office of Communication, Information Disclosure, Training, and Education (OCITE); abolished the Digital Communication Media Staff; established the Office of Communication and Content Development (OCCD) and the Office of Training and Education (OTE) within OCITE, established the Division of Digital Communication and Marketing (DDCM) within OCCD, and realigned the existing divisions to the new offices.

DCCE. ORGANIZATION. CDRH's OCITE is headed by the Director, and includes the following:

Office of Communication, Information Disclosure, Training, and Education (DCCE)

Program Management Operations Staff (DCCE1)

Office of Communication and Content Development (DCCEE)

Division of Communication (DCCEEA)

Division of Information Disclosure (DCCEEB)

Division of Digital Communication and Marketing (DCCEEC)

Office of Training and Education (DCCEF)

Division of Employee Training and Development (DCCEFA)

Division of Industry and Consumer Education (DCCEFB)

## 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.*

[FR Doc. 2024-09381 Filed 5-6-24; 8:45 am]

BILLING CODE 4164-01-P

## 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

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## III. Electronic Access

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

### Xavier Becerra,

*Secretary, Department of Health and Human Services.*

[FR Doc. 2024-09382 Filed 5-6-24; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-1917]

#### Fresenius Kabi USA, LLC, et. al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of June 6, 2024.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New