

Investigational Drugs Under an IND: Questions and Answers.” FDA issued a revised draft guidance of the same title in August 2022 to include responses to stakeholder questions received since publication of the final guidance in 2016. This guidance finalizes the revised draft guidance issued on August 23, 2022 (87 FR 51679). FDA considered comments received on the revised draft guidance as the guidance was finalized. Changes from the revised draft to the final guidance address the inclusion of information about charging for investigational drugs in the informed consent document and provide the definition of intermediate-size patient population expanded access. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Charging for Investigational Drugs Under an IND: Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: February 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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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), Office of the Commissioner (OC), Office of Digital Transformation (ODT) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on December 21, 2023.

FOR FURTHER INFORMATION CONTACT:

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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 revised to reflect the FDA, OC’s ODT.

The proposed changes to ODT’s organizational structure consolidate similar functions and resources across multiple areas and align the organizational structure with federal and industry standards. This will create a more agile organization, improve resource management, enhance customer service, and better align the name of organizational components with current functions. The reorganization will maintain a reasonable span of control and clear and appropriate lines of authority and responsibilities between organizations. This will also ensure optimal resource utilization and leveraging of existing staff talent and will allow ODT more efficiency and effectiveness in the advancement of continuous improvement efforts.

This reorganization elevates the functions and resources of the Office of Enterprise Portfolio Management in the Office of Information Management and Technology (OIMT) to the Office of Digital Transformation; established the

Division of Acquisition Innovation, Division of Technology Business Management, and the Division of Finance and Budget within OEPM; and realigned the Delivery Management Support Staff from the Office of Technology and Delivery (OTD) to OEPM, Division of Acquisition Innovation; established the Acquisitions Operations Branch, Acquisition Governance Branch, and IT Asset Management Branch within the Division of Acquisition Innovation; established the IT Governance Branch and Business Intelligence Branch within the Division of Technology Business Management; establish the Budget Formulation Branch and Budget Execution Branch within the Division of Finance and Budget; established the Office of Organizational Excellence (OEX) reporting to the ODT; established the Division of People and Culture (DPC) and the Division of Knowledge and Communications (DKC) within OEX; realigned the staff resources and functions from the OBCA Division of Management Services (DMS) to DPC in OEX; established the Talent Strategy Staff (TSS) and the Executive Services Staff (ESS) within OEX; abolished the Strategic Operations Staff (SOS) located in ODT Immediate Office and realigned staff resources and functions to DKC in OEX; realigned staff resources and functions from the Knowledge Management Staff (KMS) in the Office of Data, Analytics, and Research to DKC; realigned existing executive services functions and staff in the ODAR, OIMT, and ODT immediate offices to DKC; retitled the current Office of Business and Customer Assurance in OIMT to the Office of Customer Experience (OCX); abolished the Division of Management Services and Division of Business Partnerships and Support in the current Office of Business and Customer Assurance; established the Division of Collaboration Services, Division of Service Desk and Support, Division of Endpoint Management, Division of End User Services, and Division of Employee Information in the new OCX; established the Enterprise Architecture Staff in the OIMT Immediate Office; established the Division of Engineering (DE) in the OIMT Office of Technology and Delivery; established the Engineering Branch, Implementation Branch, Application Branch, and Database & Content Services Branch within DE; retitled the Division of Infrastructure Operations (DIO) in the OTD in OIMT to the Division of Infrastructure Services (DIS); abolished the Infrastructure Management Services Staff (IMSS) within DIO and realigned

the staff resources and functions to the DIS immediate office; abolished the DIO's Implementation Branch, Infrastructure Engineering Branch, System Operations Branch, Network and Communications Operations Branch, Systems Monitoring and Response Branch, and Systems Monitoring and Response Branch; established the Network Services Branch, Systems Services Branch, and Operations Branch in DIS; realigned staff resources based on their roles and responsibilities; abolished the Delivery Management Support Staff (DMSS) within OTD immediate office; abolished the Application Management Services Staff, Medical Products Branch, OC/CVM/CTP Branch, ORA/CFSAN/CVM Branch, Enterprise Applications Branch, Data Management and Operations Branch within OIMT/OTD/Division of Application Services (DAS); established the Regulatory Operations Branch, Scientific Operations Branch, and Business & Post-Market Branch within DAS; retitled the Office of Data, Analytics, and Research (ODAR), Data Staff to the Analytics Staff; retitled the ODAR Health Informatics Staff to the Informatics Staff; established the Data and Analytics Governance Staff and Data Strategy and Services Staff within ODAR; abolished the Knowledge Management Staff (KMS) within ODAR and realigned the staff resources and functions to the Office of Organizational Excellence, Division of Knowledge & Communications; established the Division of Cybersecurity Capabilities (DCC), Division of Risk & Compliance (DRC), Division of Cybersecurity Operations (DCO), and the Division of Counterintelligence & Insider Threat (DCIT) within the Office of Information Security (OIS); established the Vulnerability Management Branch and Identity Management Branch under OIS/DCC; established the Information System Security Branch and Risk Compliance and Audit Branch under OIS/DRMC; established the CIOCC Operations Branch and Network Security Branch under OIS/DCO; established the Program Staff within the OIS immediate office; realigned OIS staff resources and functions within OIS based on their roles and responsibilities.

The Food and Drug Administration Office of the Commissioner's Office of Digital Transformation is headed by the Chief Information Officer and has been restructured as follows:

Office of Digital Transformation (DCAD)
Office of Information Management and Technology (DCADA)
Enterprise Architecture Staff (DCADA1)
Office of Technology and Delivery (DCADAA)

Division of Infrastructure Services (DCADAAA)
Network Services Branch (DCADAAA1)
Systems Services Branch (DCADAAA2)
Operations Branch (DCADAAA3)
Division of Application Services (DCADAAB)
Regulatory Operations Branch (DCADAAB1)
Scientific Operations Branch (DCADAAB2)
Business and Post-Market Branch (DCADAAB3)
Division of Engineering (DCADAAC)
Engineering Branch (DCADAAC1)
Implementation Branch (DCADAAC2)
Application Branch (DCADAAC3)
Database & Content Services Branch (DCADAAC4)
Office of Customer Experience (DCADAB)
Division of Collaboration Services (DCADABA)
Division of Service Desk and Support (DCADABB)
Division of Endpoint Management (DCADABC)
Division of End User Services (DCADABD)
Division of Employee Information (DCADABE)
Office of Information Security (DCADB)
Program Staff (DCADB1)
Division of Cybersecurity Capabilities (DCADBA)
Vulnerability Management Branch (DCADBA1)
Identity Management Branch (DCADBA2)
Division of Risk and Compliance (DCADBB)
Information System Security Branch (DCADBB1)
Risk Compliance and Audit Branch (DCADBB2)
Division of Cybersecurity Operations (DCADBC)
CIOCC Operations Branch (DCADBC1)
Network Security Branch (DCADBC2)
Division of Counterintelligence/Insider Threat (DCADBD)
Office of Data, Analytics, and Research (DCADC)
Analytics Staff (DCADC1)
Informatics Staff (DCADC2)
Data and Analytics Governance Staff (DCADC4)
Data Strategy and Services Staff (DCADC5)
Office of Enterprise Portfolio Management (DCADD)
Division of Acquisition Innovation (DCADDA)
Acquisitions Operations Branch (DCADDA1)
Acquisitions Governance Branch (DCADDA2)
IT Asset Management Branch (DCADDA3)

Division of Technology Business Management (DCADDB)
IT Governance Branch (DCADDB1)
Business Intelligence Branch (DCADDB2)
Division of Finance and Budget (DCADDC)
Budget Formulation Branch (DCADDC1)
Budget Execution Branch (DCADDC2)
Office of Organizational Excellence (DCADE)
Talent Strategy Staff (DCADE1)
Executive Services Staff (DCADE2)
Division of People and Culture (DCADEA)
Employee Experience Branch (DCADEA1)
Learning and Development Branch (DCADEA2)
Division of Knowledge and Communications (DCADEB)
Knowledge and Innovation Branch (DCADEB1)
Communications and Outreach Branch (DCADEB2)

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 Staff Manual Guide 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 of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906-0061

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.