Authority: The CAPTA Reauthorization Act of 2010; Title II of the CAPTA, Pub. L. 115–271 (42 U.S.C. 5116 *et seq.*).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–03107 Filed 2–14–24; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0447]

Charging for Investigational Drugs Under an Investigational New Drug Application: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Charging for Investigational Drugs Under an IND: Questions and Answers.'' This guidance addresses frequently asked questions related to the implementation of FDA's regulation on charging for investigational drugs under an investigational new drug application (IND) for the purpose of either clinical trials or expanded access for treatment use. This guidance finalizes the revised draft guidance of the same title issued on August 23, 2022, and replaces the final guidance issued on June 3, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on February 15, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–0447 for ''Charging for Investigational Drugs Under an IND: Questions and Answers'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926, *Dat.Doan@fda.hhs.gov*; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Charging for Investigational Drugs Under an IND: Questions and Answers.'' FDA's regulation on charging for investigational drugs under an IND (21 CFR 312.8) for the purpose of either clinical trials or expanded access for treatment use allows sponsors to charge for investigational drugs under certain circumstances.

FDA issued a final guidance on June 3, 2016 entitled ''Charging for

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.

[FR Doc. 2024–03186 Filed 2–14–24; 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), 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: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management; Office of Finance, Budget, Acquisitions, and Planning; 4041 Powder Mill Road, Beltsville, MD 20705–4304; 301–796–3843.

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