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–2023–D–4974 for ''Advanced Manufacturing Technologies Designation Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Ranjani Prabhakara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993, 240–402–4652; 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.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 13, 2023, FDA published a notice of availability with a 60-day comment period to provide comments on the draft guidance entitled ''Advanced Manufacturing Technologies Designation Program'' and its proposed collection of information. FDA has received requests to extend the comment period to allow sufficient time to develop and submit meaningful comments. FDA has considered the requests and is extending the comment period for 30 days, until March 13, 2024. The Agency believes that this extension allows adequate time for interested persons to submit comments.

II. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: February 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02836 Filed 2–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0119]

Fiscal Year 2024 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''FY 2024 Generic Drug Science and Research Initiatives Workshop.'' The purpose of the public workshop is to provide an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—

industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2022 (GDUFA III) to develop an annual list of science and research initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2025 Generic Drug User Fee Amendments (GDUFA) science and research initiatives.

DATES: The public workshop will be held on May 20 and 21, 2024. Either electronic or written comments on this public workshop must be submitted by June 21, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in person and will be accessible virtually. Registrants will have an opportunity to indicate their interest in attending the public workshop in person. If there are restrictions imposed by applicable health guidelines for in-person gatherings, or seating capacity limitations, registrants interested in attending the public workshop in person will be contacted. The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 21, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–N–0119 for ''FY 2024 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Sam Raney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4732, Silver Spring, MD 20993, 240–402–7967, *Sameersingh.Raney@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240–402–7957, *Robert.Lionberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112–144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA I commitment letter) to work with industry and interested stakeholders on identifying science and research initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA was reauthorized until September 2022 through the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Pub. L. 115–52), and in September 2022, GDUFA was reauthorized until September 2027 through the Generic Drug User Fee Amendments of 2022 (GDUFA III) (Pub. L. 117–180, 136 Stat. 2155). In the GDUFA Reauthorization

Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III commitment letter),[1] FDA agreed to conduct annual public workshops ''to solicit input from industry and stakeholders for inclusion in an annual list of GDUFA III regulatory science initiatives.'' This public workshop scheduled for May 20 and 21, 2024, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to obtain input from industry and other interested stakeholders on identifying generic drug science and research initiatives for FY 2025. FDA is interested in receiving input about regulatory science initiatives for the ongoing years of the GDUFA III science and research program, and particularly for FY 2025.

Topics discussed during the workshop will focus on research that is needed to address scientific knowledge gaps and associated challenges impacting the development and regulatory assessment of generic products, including complex generics. As examples, topics discussed will likely relate to nitrosamine drug substance-related impurities, drug-device combination products, predictive tools to improve the efficiency of generic product development, and other topics that can enhance public access to high quality, safe and effective generic products. Specific presentations and discussions at this workshop will be announced at a later date and may differ from the topics above. Input about the topics above will help the Agency identify and expand its scientific focus for the next fiscal year.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2025 science and research initiatives. Information concerning the science and research initiatives for generic drugs can be found on the Science & Research website at *https://www.fda.gov/drugs/generic-drugs/science-research.*

III. Participating in the Public Workshop

Registration: Registration is free. Persons interested in attending this public workshop must register online at *https://fda.zoomgov.com/webinar/register/WN_qwJcEJcWQeeglLeZMD2MCg.* Registration may be performed at any time before or during the workshop.

If you need special accommodations due to a disability, please contact FDA via email at *GDUFARegulatoryScience@fda.hhs.gov* no later than 11:59 p.m. eastern time on May 10, 2024.

Requests for Oral Presentations: During online registration you may indicate if you wish to present your public comments. Requests to provide public comments via a pre-recorded presentation or a live presentation, including in-person or virtual presentations, should be submitted via email to *GDUFARegulatoryScience@fda.hhs.gov* by 11:59 p.m. Eastern Time on March 8, 2024. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the workshop. Based upon the public comment presentation requests received by March 8, 2024, at 11:59 p.m. eastern time, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin; we will select and notify participants by April 1, 2024. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than May 10, 2024, 11:59 p.m. eastern time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. Please register online (as described above) to attend the workshop remotely (virtually). Registrants will receive a hyperlink that provides access to the webcast on both days. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a video recording and audio transcript of the public workshop are available, they will be accessible at *https://www.regulations.gov* or via the Science & Research FDA website accessible at *https://www.fda.gov/drugs/generic-drugs/science-research.* They may also be available for viewing at the Dockets Management Staff (see **ADDRESSES**).

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02841 Filed 2–9–24; 8:45 am]

BILLING CODE 4164–01–P

[1] The GDUFA III commitment letter is available at *https://www.fda.gov/media/153631/download.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0945–0005]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 12, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov, PRA@hhs.gov,* or by calling (202) 264–0041.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0945–0005 and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@hhs.gov,* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HIPAA Audit Review Survey.

Type of Collection: Reinstatement, with Change, of a Previously Approved Collection OMB No. 0945–0005: Office for Civil Rights (OCR)—Health Information Privacy Division.

Abstract: This information collection consists of 39 online survey questions that will be sent to 207 covered entities and business associates that participated in the 2016–2017 OCR HIPAA Audits. The survey will gather information relating to the effect of the audits on the audited entities and the entities' opinions about the audit process.

OCR is conducting a review of the 2016–2017 HIPAA Audits to determine its efficacy in assessing the HIPAA compliance efforts of covered entities.