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.

As part of that review, the online survey will be used to:

Measure the effect of the 2016–2017 HIPAA Audits on covered entities' and business associates' subsequent actions to comply with the HIPAA Rules.

Provide entities with an opportunity to give feedback on the Audit and its features, such as the helpfulness of HHS' guidance materials and communications, the utility of the online submission portal, whether the Audit helped improve entity compliance, and the entities' responses to the Audit-report findings and recommendations.

Provide OCR with information on the burden imposed on entities to collect audit-related documents and to respond to audit-related requests; and

Seek feedback on the effect of the HIPAA Audit program on the entities' day-to-day business operations.

The information, opinions, and comments collected using the online survey will be used to improve future OCR HIPAA Audits.

ANNUALIZED BURDEN HOUR TABLE

Form name	Respondents	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
OCR HIPAA Audit Participant Survey.	Covered Entity Privacy and Security Officer(s) or Administrators.	166	1	45/60	124.5
OCR HIPAA Audit Participant Survey.	Business Associate Privacy and Security Officer(s) or Administrators.	41	1	45/60	30.75
Total		207			155.25

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–02737 Filed 2–9–24; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Maximizing Investigators' Research Award—E Study Section, March 05, 2024, 8 a.m. to March 6, 2024, 6 p.m., Center for Scientific Review, RKL2, 6701 Rockledge Dr, Bethesda, MD, 20817 which was published in the **Federal Register** on February 06, 2024, 89 FR 8218, Doc 2024–02265.

This meeting is being amended to change the meeting start time from 8 a.m. to 9 a.m. The meeting is closed to the public.

Dated: February 6, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02775 Filed 2–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Investigator Initiated Extended Clinical Trial (R01 Clinical Trial Required).

Date: March 8, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Lindsey M. Pujanandez, Ph.D., Scientific Review Officer, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852, (240) 627–3206, *lindsey.pujanandez@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 6, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02773 Filed 2–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; URGenT: Translational Efforts to Advance Gene-based Therapies for Ultra-Rare Neurological and Neuromuscular Disorders.

Date: February 27, 2024.

Time: 10:00 a.m. to 1:00 p.m.