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. 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: Keith F. Verrett Jr., Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2179, Silver Spring, MD 20993–0002, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' GDUFA II (Pub. L. 115–52, Title III), was signed into law on August 18, 2017. GDUFA II extends FDA's authority to assess and collect generic drug user fees from fiscal year (FY) 2018 through FY 2022. The extension of this user fee authority under GDUFA II continues FDA's and industry's ability to meet the goals of improving public access to safe and effective generic drugs and enhancing the predictability of the review process.

The guidance announced in this notice replaces the draft guidance for industry on ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017,'' dated October 2019 and published in November 2019. This guidance addresses changes in user fee assessments from GDUFA I, user fees incurred by industry under GDUFA II, payment procedures, reconsideration and appeals, and other additional information to assist industry in complying with GDUFA II. This guidance also describes how FDA determines affiliation for purposes of assessing generic drug user fees.

FDA has reviewed the comments submitted to the docket and determined that the comments do not require substantive changes from the draft guidance. Clarifying language was, however, added to this final guidance largely based on the public comments and to update the Agency's treatment of sponsor requests for ''transfer'' of certain user fee payments eligible for refund toward applicable user fee liabilities.

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 ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in Form FDA 3913 (User Fee Payment Refund Request) have been approved under OMB control number 0910–0805 and the collections of information in Form FDA 3914 (User Fee Payment Transfer Request) have been approved under OMB control number 0910–0805.

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,* or *https://www.regulations.gov.*

Dated: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10702 Filed 5–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–xxxx]

Agency Father Generic 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 July 18, 2022.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

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: National Strategy for a Resilient Public Health Supply Chain Paper Reduction Act Clearance.

Type of Collection: Father Generic ICR.

OMB No. 0990–XXXX—Assistant Secretary for Preparedness and

Response—Office of Strategy, Policy, Planning, and Requirements.

Abstract

The Department of Health and Human Services, HHS, Assistant Secretary for Preparedness and Response, within Office of Strategy, Policy, Planning, and Requirements is seeking approval by OMB on a new Generic clearance. HHS, is working with the White House and across the federal interagency to launch a multiyear implementation involving the identification and coordination of measurable activities across the U.S. government, SLTT (State, Local, Tribal, and Territorial) jurisdictions, and private sector partners. Cross-sectoral engagement is the underpinning of many of the interdependent implementation activities. For example, one such activity involves information collection from SLTT partners on facility, local, and state stockpiling plans to ensure coordinated plans are in place for a future public health emergency. Potential engagements include surveys, stakeholder meetings, RFI's, town hall meetings, and workshops. With each of these different mechanisms of engagement, there is a varied frequency ranging from single engagements to regularly recurring meetings.

In July 2021, the White House published the National Strategy for a Resilient Public Health Supply Chain. The strategy calls out strategic goals and recommendations for building immediate and long-term resilience through increased visibility, agility, and robustness in the public health supply chain to prepare for and mitigate future public health emergencies.

HHS is requesting a 3-year PRA clearance and will engage with SLTT, trade groups, mixed cross-sector audiences, non-governmental organizations, manufacturers, academia, healthcare providers and facilities, and local communities.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Stakeholder Meetings	Private Sector, Manufacturers, U.S. Government Supply Chain Inventory Holders.	30	6	6	1080
RFIs	Private Sector, Mixed Cross-Sector Audience, Manufacturers, SLTT partners.	40	1	40	1600
Workshops	Private Sector, SLTT partners, Trade Groups, Manufacturers, Academia, Healthcare Providers/ Facilities, Public.	50	4	8	1600
Surveys	Private Sector, SLTT partners, Trade Groups, Manufacturers, Academia.	75	1	1	75
Total			12		4355

Sherrette A. Funn,

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

[FR Doc. 2022–10700 Filed 5–17–22; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Child Health and Human Development Initial Review Group; Health, Behavior, and Context Study Section.

Date: June 13, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Kimberly L. Houston, MD, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892, (301) 827–4902, *kimberly.houston@nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Function, Integration, and Rehabilitation Sciences Study Section.

Date: June 17, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137D, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Helen Huang, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137D, Bethesda, MD 20892, (301) 435–8207, *Helen.Huang@nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; NIH Pathway to Independence Award (Parent K99/R00 Independent Clinical Trial Not Allowed)/ Member Conflict.

Date: June 24, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2127D, Bethesda, MD 20892 (Video Assisted Meeting).