ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Implementation Plan Guidance for Development and Implementation Grantees	27	1	450	12,150	4,050
DIG Community Needs and Readiness Assessment	27	1	450	12,150	4,050
Totals:				24,300	8,100

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Title V of the Social Security Act, sections 511(e)(8)(A) & 511(h)(2)(A)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–00556 Filed 1–13–25; 8:45 am]

BILLING CODE 4184–77–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5890]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with our generic drug user fee program.

DATES: Either electronic or written comments on the collection of information must be submitted by March 17, 2025.

ADDRESSES: 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 March 17, 2025. 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–2024–N–5890 for ''Generic Drug User Fee 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.

FOR FURTHER INFORMATION CONTACT: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Drug User Fee Program

OMB Control Number 0910–0727—Revision

This information collection helps support implementation of FDA's Generic Drug User Fee Program (GDUFA), most recently reauthorized September 30, 2022. It includes information collections discussed in the document, ''GDUFA Reauthorization Performance Goals And Program Enhancements Fiscal Years 2023–2027,'' commonly referred to as the ''Goals Letter'' or ''Commitment Letter.'' The Commitment Letter represents the product of FDA discussions with the regulated industry and public stakeholders, as mandated by Congress. The Goals Letter identifies current GDUFA program objectives and general procedures for communicating with FDA. Agency guidance, as outlined in the Goals Letter, are utilized in the information collection. All Agency guidance documents are issued consistent with our Good Guidance Practice regulations (21 CFR 10.115), which provide for public comment at any time, as well as regulatory authority found in 21 CFR 314.445 (Guidance documents), currently approved in OMB control number 0910–0001.

The information collection also includes Form FDA 3974, the Generic Drug User Fee Cover Sheet and associated instructions, available for download at *https://userfees.fda.gov/OA_HTML/GDUFAFacilityCScreation.pdf.* Form FDA 3974 is used to provide a uniform format for the submission of information necessary to account for and track user fees, and to determine the amount of the fee required.

As we communicate on our website, potential applicants are encouraged to contact the FDA Generic Drugs Program with questions at any point in their development and application preparation processes. We have revised the information collection to include the submission of ''controlled correspondence'' within the scope of activity, including covered product authorizations (CPAs) provided for under the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act) (Pub. L. 116–94). Historically, and under the terms of the GDUFA, a controlled correspondence may be submitted by or on behalf of a generic drug manufacturer or related industry prior to submitting an abbreviated new drug application (ANDA). To provide respondents with assistance regarding the submission of controlled correspondence, we continue to develop and issue topic-specific Agency guidance, including the following documents:

- Controlled Correspondence Related to Generic Drug Development (Controlled Correspondence Guidance), (*https://www.fda.gov/media/164111/download,* March 2024)
- Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA, (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-specific-guidance-meetings-between-fda-and-anda-applicants-under-gdufa,* February 2023)
- Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-anda-applicants-complex-products-under-gdufa-guidance-industry,* October 2022)
- Competitive Generic Therapies Guidance (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/competitive-generic-therapies,* October 2022)
- Cover Letter Attachments for Controlled Correspondences and ANDA Submissions (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cover-letter-attachments-controlled-correspondences-and-anda-submissions,* June 2023)
- How to Obtain Covered Product Authorization (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-covered-product-authorization,* September 2022)

Each guidance document may be downloaded from our website where we maintain a searchable database at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

FDA estimates the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5 (30 minutes)	1,904
Submission of Controlled Correspondence as Discussed in Agency Topic-Specific Guidance Documents	400	12.5	5000	5	25,000
Total	.....	.....	8,808	.....	26,904

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated is based on available Agency data. Our burden estimate reflects an overall increase attributable to the inclusion of controlled correspondence and new generic drug product CPA requests.

Dated: January 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00564 Filed 1–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Physician-Focused Payment Model Technical Advisory Committee; Meetings

ACTION: Notice of meetings.

SUMMARY: This notice announces the 2025 meetings of the Physician-Focused Payment Model Technical Advisory Committee (PTAC). These meetings include deliberation and voting on proposals for physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities and may include discussions on topics related to current or previously submitted PFPMs. All meetings are open to the public.

DATES: The 2025 PTAC meetings will occur on the following dates:

- Monday–Tuesday, March 3–4, 2025, from 9 a.m. to 5 p.m. ET
- Tuesday–Wednesday, June 3–4, 2025, from 9 a.m. to 5 p.m. ET
- Monday–Tuesday, September 8–9, 2025, from 9 a.m. to 5 p.m. ET
- Tuesday–Wednesday, December 9–10, 2025, from 9 a.m. to 5 p.m. ET

Please note that times are subject to change. If the times change, the ASPE PTAC website will be updated (*https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee*) and registrants will be notified directly via email.

ADDRESSES: All PTAC meetings will be held virtually and/or in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC, 20201.

FOR FURTHER INFORMATION CONTACT: Lisa Shats, Designated Federal Officer at *Lisa.Shats@hhs.gov* (202) 875–0938.

SUPPLEMENTARY INFORMATION:

Agenda and Comments. PTAC will hear presentations on proposed PFPMs that have been submitted by individuals and stakeholder entities and/or discussion on topics related to current or previously submitted PFPMs. Regarding proposed PFPMs, following each presentation, PTAC will deliberate on the proposed PFPM. If PTAC completes its deliberation, PTAC will vote on the extent to which the proposed PFPM meets criteria established by the Secretary of Health and Human Services and on an overall recommendation to the Secretary (if applicable). Time will be allocated for public comments. The agenda and other documents will be posted on the PTAC section of the ASPE website, *https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee,* prior to the meeting. The agenda is subject to change. If the agenda does change, registrants will be notified directly via email, the website will be updated, and notification will be sent out through the PTAC email listserv (*https://list.nih.gov/cgi-bin/wa.exe?A0=PTAC* to subscribe).

Meeting Attendance. These meetings are open to the public and may be hosted in-person or virtually. We intend that in-person meetings will be held in the Great Hall of the Hubert H. Humphrey Building. The public may attend in person, when feasible, virtually, or view the meeting via livestream at *www.hhs.gov/live.* Information about how to access the meeting virtually or via livestream will be sent to registrants prior to the meeting; and a telephone number will be sent to registrants participating via the dial-in only option prior to the meeting. Space may be limited, and registration is preferred. When registration opens, a link to the registration page will be available at *https://aspe.hhs.gov/collaborations-committees-advisory-groups/ptac/ptac-meetings prior to the meeting.* Registrants will receive a confirmation email shortly after completing the registration process.

Special Accommodations. If sign language interpretation or other reasonable accommodation for a disability is needed, please contact *PTAC@hhs.gov,* no later than two weeks prior to the scheduled meeting.

Authority. 42 U.S.C. 1395(ee); section 101(e)(1) of the Medicare Access and CHIP Reauthorization Act of 2015; section 51003(b) of the Bipartisan Budget Act of 2018.

PTAC is governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C app.), which sets forth standards for the formation and use of federal advisory committees.

Dated: January 3, 2025.

Tisamarie B. Sherry,

Deputy Assistant Secretary for Behavioral Health, Disability and Aging Policy, Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2025–00612 Filed 1–13–25; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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