limited; therefore, FDA may limit the number of in person participants from each organization.

If you need special accommodations due to a disability, please contact Dat Doan [see **FOR FURTHER INFORMATION CONTACT**] no later than June 27, 2025.

Opportunity for Public Comment: Those who register online by June 16, 2025, at 11:59 p.m. Eastern Time will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. All requests to make a public comment during the meeting must be received by June 27, 2025, 11:59 p.m. Eastern Time. 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 comments and request time jointly. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by July 9, 2025. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming of the Public Meeting: This public meeting will also be webcast. Please visit the following website to register: *https://GDUFAIVReauthorizationKickoff.eventbrite.com.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufa.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: May 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08872 Filed 5–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0816]

Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2028 through 2032. PDUFA authorizes FDA to collect user fees to support the process for the review of human drug applications. The current legislative authority for PDUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting prescription drug user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) directs that FDA begin the PDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input and holding a public meeting where the public may present its views on the reauthorization. FDA invites public comment as the Agency begins the process to reauthorize the program in FYs 2028 through 2032. These comments will be published and available on FDA's website.

DATES: The hybrid public meeting will be held on July 14, 2025, from 9 a.m. to 2 p.m., and will take place in person and virtually. Submit either electronic or written comments on this public meeting by August 14, 2025.

ADDRESSES: The public workshop will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002 and virtually using the Microsoft Teams platform. Entrance for the public meeting 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 on August 14, 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–2025–N–0816 for ''Reauthorization of the Prescription Drug User Fee Act; Public Meeting; 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: Andrew Kish, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–5215, *Andrew.Kish@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a hybrid public meeting to begin the reauthorization process for PDUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of human drugs, which reaches various components in FDA, including the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of the Commissioner (OC), and the Office of Inspections and Investigations (OII). The current authorization of the program (PDUFA VII) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process. Section 736B(f)(2) of the FD&C Act (21 U.S.C. 379h–2(f)(2)) requires that before FDA begins negotiations with the regulated industry on PDUFA reauthorization, the Agency performs the following: (1) publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting where the public may present its views on the reauthorization; (3) provide a period of 30 days after the public meeting to obtain written comments from the public; and (4) publish the comments on FDA's website. This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA website will satisfy these requirements. The purpose of the meeting is to hear stakeholder views on PDUFA as we consider the features to propose, update, discontinue, or add in the next PDUFA. FDA is interested in responses to the following three questions and welcomes any other pertinent information stakeholders would like to share:

- What is your assessment of the overall performance of PDUFA VII thus far?
- What current features of PDUFA should be reduced or discontinued to ensure the continued efficiency and effectiveness of the human drug review process?
- What new features, if any, FDA consider adding to the program to enhance the efficiency and effectiveness of the human drug review process?
- What changes, if any, could be made to the current fee structures and amounts to better advance the goals of the agreement, including facilitating product development and timely access for consumers?

II. What is PDUFA and what does it do?

The following information is provided to help potential meeting participants better understand the history and evolution of PDUFA and its status. PDUFA is a law that authorizes FDA to collect fees from drug companies that submit marketing applications for certain human drug and biological products. PDUFA was originally enacted in 1992 as the Prescription Drug User Fee Act for a period of 5 years.

In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA) which renewed the program (PDUFA II) for an additional 5 years. Congress extended PDUFA again for another 5 years (PDUFA III), through FY 2007, in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In 2007, Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) reauthorized PDUFA through FY 2012 (PDUFA IV) and in 2012 the Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized the law again through FY 2017 (PDUFA V). Congress reauthorized PDUFA through FY 2022 in 2017 under Title I of the FDA Reauthorization Act of 2017 (FDARA) (PDUFA VI). PDUFA was most recently renewed in 2022 under Title 1 of the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) which lasts through FY 2027 (PDUFA VII).

PDUFA's intent is to provide additional revenues so that FDA can hire more staff, improve systems, and establish a better managed human drug review process to make important therapies available to patients sooner without compromising review quality or FDA's high standards for safety, efficacy, and quality. As part of FDA's negotiated agreement with industry during each reauthorization, the Agency agrees to certain performance and procedural goals and other commitments that apply to aspects of the human drug review program. These goals apply, for example, to the process for the review of original new human drug and biological product applications, postmarket safety activities, and new data standards and technology enhancements.

During the first few years of PDUFA I, the additional funding enabled FDA to eliminate backlogs of original applications and supplements. Phased in over the 5 years of PDUFA I, the goals were to review and act on 90 percent of priority new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements within 6 months of submission of a complete application; to review and act on 90 percent of standard original NDAs, BLAs, and efficacy supplements within 12 months, and to review and act on resubmissions and manufacturing supplements within 6 months. Over the course of PDUFA I, FDA exceeded all these performance goals and significantly reduced median review times of both priority and standard NDAs and BLAs.

Under PDUFA II, the review performance goals were adjusted, and new procedural goals were added to improve FDA's interactions with industry sponsors and to help facilitate the drug development process. The procedural goals, for example, articulated time frames for scheduling sponsor-requested meetings intended to address issues or questions regarding specific drug development programs, as well as time frames for the timely response to industry-submitted questions on special study protocols. FDA met or exceeded all the review and procedural goals under PDUFA II. However, concerns grew that overworked review teams often had to return applications as ''approvable'' because they did not have the resources and sufficient staff time to work with the sponsors to resolve issues so that

applications could be approved in the first review cycle.

A sound financial footing and support for limited postmarket risk management were key themes of PDUFA III. Base user fee resources were significantly increased and a mechanism to account for changes in human drug review workload was adopted. PDUFA III also expanded the scope of user fee activities to include postmarket surveillance of new therapies for up to 3 years after marketing approval. FDA committed to the development of guidance for industry on risk assessment, risk management, and pharmacovigilance, as well as guidance to review staff and industry on good review management principles (GRMPs). Initiatives to improve application submission and Agency-sponsor interactions during the drug development and application review processes were also adopted.

With PDUFA's reauthorization under FDAAA Title I (PDUFA IV), FDA obtained a significant increase in base fee funding and committed to full implementation of GRMPs, which included providing a planned review timeline for premarket review, development of new guidance for industry on innovative clinical trials, modernization of postmarket safety, and elimination of the 3-year limitation on fee support for postmarket surveillance. Additional provisions in FDAAA (Titles IV, V, and IX) gave FDA additional statutory authority that increased the pre- and postmarket review process requirements, added new deadlines, and effectively increased review workload. Specifically, the new provisions expanded FDA's drug safety authorities, such as the authority to require risk evaluation mitigation strategies, order safety labeling changes, and require postmarket studies.

Under Title I of FDASIA, the fourth renewal of PDUFA, FDA implemented a new review program (the Program) to promote greater transparency and increase communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applied to all new molecular entity (NME) NDAs and original BLAs received by the Agency from October 1, 2012, through September 30, 2017. The Program added new opportunities for communication between the FDA review team and the applicant during review of a marketing application, including midcycle communications and late-cycle meetings, while adding 60 days to the review clock to provide for this increased interaction and to address review issues for these complex applications. PDUFA V also required an assessment of the impact of the Program. The independent assessment of the Program entitled ''Assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs in PDUFA V,'' is available at: *https://www.fda.gov/media/101907/download.*

In addition to continued commitment to a significant set of review, processing, and procedural goals, PDUFA V also included commitments related to enhancing regulatory science and expediting drug development, enhancing benefit-risk assessment in regulatory decision making, modernizing the FDA drug safety system, and improving the efficiency of human drug review by requiring electronic submissions and standardization of electronic drug application data.

In August 2017, FDARA was enacted, renewing the prescription drug user fee program for a sixth time. This iteration of the program continued and built upon the successes of PDUFA V. In PDUFA VI, FDA and industry members agreed to continue the Program model developed in PDUFA V to continue to promote the efficiency and effectiveness of the first cycle review process. PDUFA VI included commitments to enhance regulatory science and expedite drug development by focusing on enhancing communication between FDA and sponsors during drug development, early consultation on the use of new surrogate endpoints, and exploring the use of real-world evidence for use in regulatory decision making, among other enhancements. This iteration included commitments to enhance the use of regulatory tools to support drug development and review through incorporation of the patient's voice in drug development, expanded use of a benefit-risk framework in drug reviews, and advancing the use of complex innovative trial designs and model informed drug development.

Under PDUFA VI, FDA also modernized the user fee structure to improve program funding predictability, stability, and administrative efficiency. The new structure eliminated the supplement fees, replaced the establishment and product fees with a program fee, and shifted a greater proportion of the target revenue to the new more predictable and stable annual program fee. The agreement also included commitments to enhance management of user fee resources through the development of a resource capacity planning capability and financial transparency activities. PDUFA VI included several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system.

The current authorization of PDUFA (PDUFA VII) introduces new enhancements to address changes in the drug development landscape, along with building on successful enhancements and refining elements from previous authorizations. The PDUFA VII agreement strengthened staff capacity and capability in CBER to support the development, review, and approval of cell and gene therapy products. It incorporates new allergenic extract products into the PDUFA program and provides resources for review of those products. The agreement introduces timelines and performance goals for pre-approval review of postmarketing requirements and use-related risk analysis and human factor protocol submissions. It also includes two new meeting types (Type D and INTERACT) to allow for focused discussion around specific and novel issues. PDUFA VII introduces four new pilot programs focused on advancing different aspects of drug development and review, including rare diseases (Rare Diseases Endpoint Advancement Pilot), real-world evidence (Advancing Real-World Evidence Program), manufacturing (Chemistry, Manufacturing, and Controls Development and Readiness Pilot), and drugs for unmet therapeutic areas (Split Real Time Application Review). The agreement continues paired meeting programs (Model-Informed Drug Development Paired Meeting Program and Complex Innovative Trial Design Meeting Program) that target complex applications. It introduces a series of new enhancements related to product quality reviews, chemistry, manufacturing, controls approaches, and advancing utilization of innovative manufacturing technologies. PDUFA VII builds on the financial enhancements included in PDUFA VI to ensure optimal use of user fee resources and transparency around the use of financial resources. The agreement commits FDA to initiatives in leveraging cloud technology, modernizing the Agency's information technology systems, enhancing bioinformatics support and use of digital health technologies to support drug development and review.

More information on these commitments can be found in the PDUFA VII commitment letter at: *https://www.fda.gov/media/151712/download?attachment.* A list of the deliverables developed to meet PDUFA VII commitments is available on the FDA web page at: *https://www.fda.gov/industry/prescription-drug-user-fee-*

amendments/completed-pdufa-vii-deliverables.

III. Public Meeting Information

A. Purpose and Scope of the Meeting

In general, the public meeting's format will include presentations by FDA and other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, the prescription drug industry, and the general public. A draft agenda and other background information for the public meeting will be posted at: *https://www.fda.gov/industry/public-meeting-reauthorization-prescription-drug-user-fee-act-pdufa-07142025.*

B. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following web page: *https://publicmeetingonthereauthorizationofpdufa.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Registration is free for both in person and virtual attendance. In person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If you need special accommodations due to a disability, please contact *Andrew.Kish@fda.hhs.gov* no later than June 30, 2025.

Opportunity for Public Comment: Those who register online by June 16, 2025, at 11:59 p.m. Eastern Time will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. All requests to make a public comment during the meeting must be received by June 30, 2025, 11:59 p.m. Eastern Time. 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 comments and request time jointly. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by July 7, 2025. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is available at *https://teams.microsoft.com/l/meetup-join/19%3ameeting_OWNhMmRmMTMtYjZiOS00MWQ3LWI5MTgtOTUzMzRlNDUwMWJj%40thread.v2/0?context=%7b%22Tid%22%3a%227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22Oid%22%3a%22f8076904-2170-423d-ae92-b261e8a4d877%22%7d.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at: *https://www.fda.gov/industry/public-meeting-reauthorization-prescription-drug-user-fee-act-pdufa-07142025.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: May 7, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08824 Filed 5–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Shortage Designation Management System, OMB No. 0906–0029—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 18, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Shortage Designation Management System OMB No. 0906–0029—Extension.

Abstract: HRSA is committed to improving the health of the Nation's underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation's health workforce. The Department of Health and Human Services relies on two federal shortage designations to identify and dedicate resources to areas and populations in greatest need of providers: Health Professional Shortage Area (HPSA) designations and Medically Underserved Area/Medically Underserved Population (MUA/P) designations. HPSA designations are geographic areas, population groups, and facilities that are experiencing a shortage of health professionals. The authorizing statute for the National Health Service Corps (NHSC) created HPSAs to fulfill the statutory requirement that NHSC personnel be directed to areas of greatest need. To further differentiate areas of greatest need, HRSA calculates a score for each HPSA. There are three categories of HPSAs based on health discipline: primary care, dental health, and mental health. Scores range from 1 to 25 for primary care and mental health and from 1 to 26 for dental health, with higher scores indicating greater need. They are used to prioritize applications for NHSC Loan Repayment Program award funding and determine service sites eligible to receive NHSC Scholarship and Students-to-Service participants.

MUA/P designations are geographic areas, or population groups within geographic areas, that are experiencing a shortage of primary care health care services based on the Index of Medical Underservice. MUAs are designated for the entire population of a particular geographic area. MUP designations are limited to a particular subset of the population within a geographic area. Both designations were created to aid