collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 15, 2024.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10398 #86) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 #86/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at 410–786–4669.

SUPPLEMENTARY INFORMATION:

Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collection

1. Title of Information Collection: Section 1115 Reentry Demonstration Initiative; *Type of Information Collection Request:* New information collection request; *Use:* On April 17, 2023, CMS released a State Medicaid Directors Letter (SMDL #23–003) announcing a demonstration opportunity to support community reentry and improve care transitions for individuals who are incarcerated and who are otherwise eligible for Medicaid to receive medical assistance under title XIX. The Section 1115 Reentry Demonstration Opportunity (hereinafter, ''the Reentry Demonstration Initiative'') will allow states to offer coverage for certain pre-release services for up to 90 days prior to the individual's expected release date that could not otherwise be covered by Medicaid due to the Medicaid inmate exclusion policy. The provision is consistent with section 5032 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271), ''Promoting State Innovations to Ease Transitions Integration to the Community for Certain Individuals.''

States applying for the Reentry Demonstration Initiative must provide a minimum set of pre-release services called the ''pre-release benefit package.'' The benefit package aims to improve transitions for individuals being released from jails or prisons and returning to their communities. The benefit package must include: (1) case management to assess and address physical and behavioral health needs and health-related social needs; and (2) medication-assisted treatment services for all types of substance use disorders as clinically appropriate, with accompanying counseling. Also required in the minimum set of services is a 30-day supply of all prescription medications that have been prescribed for the beneficiary.

This collection of information request includes three templates that are intended to expedite CMS's review of reentry demonstration initiative applications and to support state implementation planning and related transparency by standardizing the presentation of key information necessary for approvals, thereby reducing rounds of clarifying questions with state applicants. The three templates include the: (1) reentry demonstration initiative preprint, (2) reentry implementation plan template, and (3) reentry budget neutrality formulation workbook. The templates are strongly encouraged but optional and described in the following section.

Form Number: CMS–10398 #86 (OMB control number: 0938–1148); *Frequency:* Annual and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 30; *Total Annual Hours:* 300. (For policy questions regarding this collection contact: Raven Smith at 410–786–3731.)

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–25503 Filed 10–31–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3575]

Reauthorization of the Over-The-Counter Monograph Drug User Fee Program; 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 Over-The-Counter [OTC] Monograph Drug User Fee Program (OMUFA) for fiscal years (FYs) 2026 through 2030. Under OMUFA, FDA collects user fees to support OTC monograph drug activities. The current legislative authority for OMUFA expires September 30, 2025. At that time, new legislation will be required to reauthorize OMUFA for future fiscal years. Following negotiations with the regulated industry and consultation with interested members of the public, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish recommendations for the reauthorization of the OMUFA program in the **Federal Register**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held on November 20, 2024, from 9 a.m. to 12:30 p.m. Submit either electronic or written comments on this public meeting by December 20, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting is scheduled to be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503, Silver Spring, MD 20993. 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/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/*

ucm241740.htm. Any changes to the public meeting location and remote information, as appropriate, will be posted to *https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa* in advance of the meeting.

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 December 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–3575 for ''Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; 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.

- 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, 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.

FOR FURTHER INFORMATION CONTACT: Kimberly Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4150, Silver Spring, MD 20993–0002, 240–705–2316, *Kimberly.Taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public meeting to discuss proposed recommendations for the reauthorization of OMUFA provisions of the FD&C Act, which authorize FDA to collect user fees to support OTC monograph drug activities. The current authorization of the program (OMUFA I) expires in September 2025. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to help fund OTC monograph drug activities. Section 744N(d) of the FD&C Act (21 U.S.C. 379j–73(d)) requires that after FDA holds negotiations with regulated industry and consults with interested members of the public, we do the following: (1) present the recommendations to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions, (2) publish the recommendations in the **Federal Register**, (3) provide a period of 30 days for the public to provide written comments on the recommendations, (4) hold a meeting at which the public may present its views on the recommendations, and (5) after consideration of public views and comments, revise the recommendations as necessary.

This **Federal Register** notice, the 30-day comment period, and the public meeting will satisfy some of these requirements. After the public meeting, we will revise the recommendations as necessary and present our recommendations to the Congressional committees.

The purpose of the public meeting announced in this **Federal Register** notice is to obtain the public's views on the proposed recommendations for the reauthorization of the OMUFA program (OMUFA II). The following information is provided to help potential meeting participants better understand the history and evolution of the OMUFA program and the current status of the proposed OMUFA II recommendations.

II. What is OMUFA and what does it do?

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (or the CARES Act; available at: *https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf*) was signed into law. The CARES Act included an important legislative initiative, detailed in amendments to the FD&C Act, that reformed and modernized the way

certain nonprescription, or OTC drugs are regulated in the United States. These drugs, commonly known as OTC monograph drugs, may be marketed without an approved drug application under section 505 of the FD&C Act (21 U.S.C. 355) if they meet the requirements of section 505G of the FD&C Act (21 U.S.C. 355g), as well as other applicable requirements. Accompanying this OTC monograph reform legislation were provisions added by the CARES Act to the FD&C Act authorizing FDA to assess and collect user fees dedicated to OTC monograph drug activities.

This user fee program with respect to OTC monograph drugs, which we refer to as OMUFA, is modeled after the successful Prescription Drug User Fee Act (PDUFA). For OMUFA purposes, industry-paid fees help support FDA's OTC monograph drug activities, and in the OMUFA I commitment letter negotiated with industry, FDA agreed to adhere to certain performance goals, including to review certain submissions within specific time frames. Similar to PDUFA, FDA anticipates that continuing this user fee program will provide additional resources to help the Agency conduct these important regulatory activities in a timely manner and ultimately help provide the public with access to innovative, safe, and effective OTC monograph drugs.

OMUFA is authorized under sections 744L and 744M of the FD&C Act (21 U.S.C. 379j–71 and 379j–72, as added by the CARES Act, under which FDA will assess and collect fees from submitters of OTC Monograph Order Requests (OMORs), other than OMORs for certain safety changes, as well as from qualifying manufacturers of OTC monograph drugs, to help support the Agency's OTC monograph drug activities.

OMUFA is intended to provide for additional funding so that FDA can hire additional staff, improve systems, and establish and better manage the Agency's OTC monograph drug activities, including making important safety-related changes to OTC monographs, as needed, and facilitating more timely availability of safe, effective, high-quality, and innovative OTC monograph drugs to the public. As part of FDA's negotiated agreement with industry regarding reauthorization, as reflected in the accompanying OMUFA commitment letter, the Agency agrees to certain performance and procedural goals and other commitments that apply to aspects of the Agency's OTC monograph drug activities. These goals apply, for example, to the review of OMORs, including safety-related OMORs.

A list of the deliverables to meet OMUFA I commitments is available on the FDA web page at *https://www.fda.gov/media/146283/download.*

III. Proposed OMUFA II Recommendations

To prepare the proposed recommendations to Congress for OMUFA reauthorization, FDA conducted discussions with the regulated industry and consulted with interested members of the public, as required by the law. We began the OMUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input on reauthorization and announcing a public meeting that was held on September 28, 2023. The meeting included presentations by FDA and a series of panels with representatives of different interested parties. The materials from the meeting, including a transcript and webcast recording, can be found at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-over-counter-monograph-drug-user-fee-program-omufa-09282023-09282023.*

Following the September 28, 2023, public meeting, FDA conducted negotiations with the regulated industry from November 2023 until June 2024. As directed by Congress, FDA posted minutes of these meetings on its website at *https://www.fda.gov/industry/fda-user-fee-programs/omufa-reauthorization-fiscal-years-2026-2030.*

The proposed recommendations for OMUFA II address many of the top priorities identified by interested members of the public, the regulated industry, and FDA. While some of the proposed recommendations are new, many either build on or refine elements from the existing program. Among the recommendations are specific proposed enhancements in the following areas: (1) OMOR review, (2) test methods, (3) meeting management, (4) education, (5) information transparency, (6) monograph product quality enhancement, and (7) financial transparency and management. The full text of the proposed OMUFA II commitment letter can be found here at *https://www.fda.gov/media/182750/download.* Each significant new or modified enhancement is described briefly below:

A. OMOR Review

The statute requires that the public have the opportunity to comment on proposed monograph orders, and thus to align with the statute, FDA is proposing in the OMUFA II commitment letter that no major amendments to an OMOR be accepted by the Agency after the public comment period for a proposed order has closed. This revision helps ensure that the public will have the opportunity to comment on any changes made to the proposed order as a result of a major amendment. The statute also gives flexibility for the public comment period on proposed orders to be extended. To acknowledge this flexibility and provide greater predictability on timing, FDA is proposing the final order goal date be extended by the same length of any public comment period extension, up to a certain amount. This is described in section I.A.2 of the proposed OMUFA II commitment letter.

The statute also specifies that filing eligibility determinations required for certain types of OMORs occur after submission of the OMOR to the Agency. In recognition that this activity takes time, FDA is proposing to extend the filing assessment period for these OMORs. This is described in section I.C.2 of the OMUFA II commitment letter. Additionally, to provide more clarity on the filing eligibility portion of the filing assessment process, FDA is proposing to draft guidance pertaining to the eligibility determination requirements and implementation. This enhancement is described in section I.I of the OMUFA II commitment letter.

B. Test Methods

Some of the test methods in OTC monographs were established decades ago and may not reflect the latest scientific methodology. To solicit general feedback from interested members of the public on issues of concern with test methods in existing monographs (final orders), FDA is proposing to issue a **Federal Register** notice followed by a crowdsourcing on FDA's crowdsourcing platform [1] to further refine the public input. This enhancement is described in section I.H.2 of the OMUFA II commitment letter.

Additionally, FDA is proposing that Congress amend the statute to add a new type of Tier Two OMOR for OMORs proposing the addition or modification of certain testing methods in OTC monographs. To qualify for this new type of Tier Two OMOR, these additional or modified testing methods would need to be reflected in a voluntary consensus standard for pharmaceutical quality established by a national or international standards

[1] See *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/fda-crowdsourcing.*

development organization and would also need to be recognized by FDA (via a process described in guidance [2]) prior to submission of the OMOR, with such recognition being made available on the FDA website. See also section I.B.1 of the OMUFA II commitment letter.

C. Meeting Management

To enhance overall meeting management, FDA is proposing a new mechanism to allow requestors to submit clarifying questions to the Agency within a certain time period following receipt of meeting minutes or a written response, in lieu of submitting a new meeting request. FDA is also proposing to expand the Type Y meeting to include requests for feedback on a protocol synopsis and to allow protocol synopsis feedback as a stand-alone topic at a Type Z meeting. Furthermore, FDA is proposing that for OMUFA performance goals to be applied to a meeting request, it must be submitted through the CDER NextGen portal (or any successor system). These enhancements are described in section I.E.1 of the proposed OMUFA II commitment letter.

Additionally, FDA recognizes that many OTC-related Advisory Committee (AdCom) meetings pertain to multiple OTC drug products and classes, rather than to products of a single requestor. The Agency also understands that impacted parties may need appropriate time to coordinate and prepare for the AdCom meeting. FDA is proposing that for this subset of OTC monograph-related AdCom meetings (where the existing policy on advance notice in FDA's 2008 Advisory Committee Meetings Guidance does not apply) that are not related to an emerging safety issue, FDA intends to announce the meeting on its website at least 100 business days in advance of the meeting. This enhancement is described in section I.E.10 of the OMUFA commitment letter.

D. Education

External parties often have questions regarding processes and procedures related to OTC-monograph related data. To better understand what questions industry and other parties have about the process FDA intends to use for obtaining data to be used in FDA-initiated generally recognized as safe (GRASE) finalizations and how industry might organize and submit data for both FDA-initiated and industry-initiated (GRASE) finalizations, FDA is proposing to run a crowdsourcing on FDA's crowdsourcing platform [3] to solicit questions about the process from interested members of the public, followed by a webinar to answer those questions for which established policy exists. This enhancement is described in section I.H.I of the proposed OMUFA II commitment letter.

FDA is also proposing hosting a webinar to detail steps about how to submit an OMOR using the NextGen Portal. This enhancement is described in section II.D of the OMUFA II commitment letter. Furthermore, FDA is proposing to issue draft guidance to provide additional information on confidentiality of information submitted to FDA in connection with proceedings under section 505G of the FD&C Act, including with respect to an OMOR. This enhancement is described in section I.1.2 of the OMUFA II commitment letter.

Furthermore, FDA is proposing to work to finalize the proposed order/draft guidance pair relating to minor changes in dosage form for solid oral OTC monograph drug products, which FDA committed to develop under the terms of the OMUFA I commitment letter. This enhancement is described in section I.J of the OMUFA II commitment letter.

E. Information Transparency

To ensure that historical information related to OTC monograph drug products is accessible to the public, FDA is proposing to post to a public docket the pre-OMUFA documents that were catalogued as part of OMUFA I. Additionally, FDA is proposing to maintain the historical status of the OTC Rulemaking website.

To help increase transparency around marketing exclusivity in the context of OTC monograph drugs, FDA is proposing to publish a web page detailing information regarding monograph-related exclusivity afforded by final orders. These enhancements are described in section II of the proposed OMUFA II commitment letter.

F. Monograph Product Quality Enhancement

To enhance monograph product quality surveillance, FDA is proposing several initiatives to help focus its efforts in this area, including vetting a certain percentage of new OTC monograph drug registrants within a certain number of months of registration to confirm whether they should be included in CDER's catalog of OTC monograph drugs and establishments. It is also proposing to update the risk-based Site Selection Model it uses to prioritize drug-related surveillance inspections and its associated manual of policy and procedure to include risk factors associated with OTC monograph drugs, as appropriate. FDA is also proposing to hold a workshop to assist industry in improving quality and compliance with current good manufacturing practice requirements.

To increase transparency around its surveillance efforts in general, FDA is proposing to report aggregate information about records requests issued to OTC monograph drug manufacturers on its website and enhance its warning letters web page.

These enhancements are described in section III of the proposed OMUFA II commitment letter.

G. Financial Transparency

To promote transparency and help focus user fee recovery efforts, FDA is proposing several mechanisms to highlight and enhance information about facilities in arrears. Proposed mechanisms include taking steps to increase the visibility of the arrears list, enhancing the list to include whether a firm is foreign or domestic and publishing on a quarterly basis a list of all facilities that have paid the OMUFA facility fee for the prior fiscal year. FDA is also proposing to publish summary registration and arrears information in the annual OMUFA financial reports and to use information from records requests issued to OTC monograph drug manufacturers to focus outstanding user fee recovery efforts. This enhancement is described in section IV of the proposed OMUFA II commitment letter.

H. Financial Management

The current overall OMUFA fee structure and the fee setting process were established by Congress for OMUFA I. There are two fee types: facility fees and OMOR fees. The process and adjustments for establishing annual target revenue for facility fees are defined in statute; the OMOR fee amounts were set in statute for the first year of OMUFA I and are adjusted for inflation each year thereafter. FDA is proposing that Congress amend the statute to make several targeted modifications to the process to enhance administrative efficiency and to ensure that FDA has adequate and timely user fee funding. Currently, the annual OMUFA facility fee due date is in June of the fiscal year, and thus not aligned with the October 1 due date for annual fees under other drug user fee programs.

[2] See FDA's guidance on ''CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality Guidance for Industry,'' available at *https://www.fda.gov/media/121305/download.*

[3] See *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/fda-crowdsourcing.*

This leads to administrative burdens and financial inefficiencies for the Agency and can be confusing for manufacturers that participate in other user fee programs. To address this issue, FDA is proposing that Congress shift the facility fee due date to October and change the liability period for annual facility fees to be the 12 months immediately preceding the start of the fiscal year for which the fees are due. The proposal also includes an option for the facility to be paid in two installments in the transition year to ease the burden on fee-paying companies.

To ensure that FDA is adequately resourced with OMUFA fees, FDA is also proposing that Congress authorize a one-time adjustment in calculating annual target revenue if the average number of fee-liable facilities exceeds a particular number in certain years of OMUFA II. This would help accommodate the additional work required to oversee these facilities. If this adjustment is made, FDA is proposing it would be part of the base revenue going forward. Additionally, FDA is proposing that Congress reset the starting base revenue for OMUFA II to include the additional direct cost adjustment from the final year of OMUFA I, which reflects funding to support information technology operations and maintenance activities.

H. Impact of OMUFA II Enhancements on User Fee Revenue

To implement the proposed enhancements for OMUFA II, user fee funding for a cumulative total of 11 full-time equivalent staff is proposed to be phased in by Congress over the course of OMUFA II. The proposed new funding will be phased in as follows, as an additional dollar amount in annual fee setting:

- $2,373,000 for FY 2026.
- $1,233,000 for FY 2027.
- $854,000 for FY 2028.

In addition, to support the other additional direct costs associated with the OMUFA II enhancements, the following amounts are proposed to be added as an additional direct cost adjustment:

- $135,000 for FY 2026.
- $300,000 for FY 2027.
- $55,000 for FY 2028.
- $30,000 for FY 2030.

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The public meeting will include a presentation by FDA and a series of invited panels representing different interested parties. For members of the public who would like to make verbal comments on the proposed enhancements and other recommendations (see instructions below), there will be a public comment period at the end of the meeting. Individuals can also submit written comments to the docket [LINK] before and after the meeting until December 20, 2024.

B. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by 11:59 p.m. Eastern Time on November 19, 2024, at *https://fda.zoomgov.com/webinar/register/WN_aW5YWtFfQiyOSzkABY3G4A#/registration.* Provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Opportunity for Public Comment: Those who register online by November 13, 2024, will have the opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, respond ''yes'' to that question in the registration form. 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. All those who wish to make a public comment during the meeting must be registered by November 13, 2024, at 11:59 p.m. Eastern Time. 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 November 18, 2024. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. The webcast for this public meeting is available at *https://fda.zoomgov.com/webinar/register/WN_aW5YWtFfQiyOSzkABY3G4A#/registration.*

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/drugs/news-events-human-drugs/public-meeting-recommendations-over-counter-monograph-drug-user-fee-program-omufa-reauthorization.*

Dated: October 28, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25458 Filed 10–31–24; 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: Data System for Organ Procurement and Transplantation Network

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 December 31, 2024.

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 Joella Roland, 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: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of Health and Human Services, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under HRSA's