

substances under the 1971 Convention at the CND meeting in March 2025.

Comments regarding the recommendations for control of *N*-pyrrolidino isotonitazene, *N*-desethyl etonitazene, and coca leaf under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03914 Filed 2–26–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0119]

Fiscal Year 2026 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled “Fiscal Year 2026 Generic Drug Science and Research Initiatives Workshop.” The purpose of the public workshop is to provide an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of interested parties—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2022 (GDUFA III) to develop an annual list of science and research initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2027 Generic Drug User Fee Amendments (GDUFA) science and research initiatives.

DATES: The public workshop will be held on June 8 and 9, 2026. Either electronic or written comments on this public workshop must be submitted by July 10, 2026. See the **SUPPLEMENTARY INFORMATION** section for additional information.

ADDRESSES: The public workshop will be held in person and will be accessible

virtually (See *Streaming Webcast of the Public Workshop* below). The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center, the Great Room (Room 1503), Silver Spring, MD 20993. Entrance for the public workshop 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>.

The procedures to submit comments are outlined below. 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 July 10, 2026. 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–2023–N–0119 for “Fiscal Year 2026 Generic Drug Science and Research Initiatives Workshop; Public Workshop; 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: Sam Raney, Ph.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4732, Silver Spring, MD 20993, 240-402-7967, Sameersingh.Raney@fda.hhs.gov; or Robert Lionberger, Ph.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240-402-7957, Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112-144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA I commitment letter) to work with industry and interested parties on identifying science and research initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA was reauthorized until September 2022 through the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Pub. L. 115-52), and in September 2022, GDUFA was reauthorized until September 2027 through GDUFA III (Pub. L. 117-180, 136 Stat. 2155). In the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter),¹ FDA agreed to conduct annual public workshops to solicit input from industry and interested parties for inclusion in an annual list of GDUFA III regulatory science initiatives. This public workshop scheduled for June 8 and 9, 2026, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to obtain input from industry and other interested parties on identifying generic drug science and research initiatives for FY 2027. FDA is interested in receiving input about regulatory science initiatives for the ongoing years of the GDUFA III science and research program, and particularly for FY 2027.

Topics discussed during the workshop will focus on research that is needed to address scientific knowledge

gaps and associated challenges impacting the development and regulatory assessment of generic products, including complex generics. As examples, topics discussed will likely focus on identifying approaches to leverage generic drug industry expertise and insights when advancing GDUFA research, and when prioritizing the development of product-specific guidances. Specific technical discussions will likely explore what new research is needed to address ongoing challenges with impurities such as nitrosamines, to expand regulatory flexibility with bioequivalence standards, to employ artificial intelligence tools in practical ways that reduce barriers for generic drug development and assessment, and to standardize product characterization test methods that support demonstrations of bioequivalence and product quality. Additional topics that can enhance public access to high-quality, safe, and effective generic products may also be discussed. Specific presentations and discussions at this workshop will be announced at a later date and may differ from the topics above. Input about the topics above will help the Agency identify and expand its scientific focus for the next fiscal year.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2027 science and research initiatives. Information concerning the science and research initiatives for generic drugs can be found on the Science & Research website at <https://www.fda.gov/drugs/generic-drugs/science-research>.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop do not need to register in advance. Those interested in attending in-person are encouraged to contact FDA at GDUFARegulatoryScience@fda.hhs.gov to confirm the availability of space prior to making travel arrangements; while there has historically been ample space to accommodate all in-person attendees, seating is limited.

If you need special accommodations due to a disability, please contact FDA via email at GDUFARegulatoryScience@fda.hhs.gov no later than 11:59 p.m. Eastern Time on May 15, 2026.

Requests for Oral Presentations: Requests to provide public comments via a prerecorded presentation or a live presentation, including in-person or virtual presentations, should be submitted via email to

GDUFARegulatoryScience@fda.hhs.gov by 11:59 p.m. Eastern Time on April 3, 2026. The request should briefly describe the topic(s) of the comments, and specify whether the comments would be presented in person or as a pre-recorded presentation. FDA will do its best to accommodate requests to make public comments that are within the scope of this public workshop, *i.e.*, those that identify what research is needed to address specific challenges for generic product development or regulatory assessment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the workshop. Based on the public comment presentation requests received by April 3, 2026, at 11:59 p.m. Eastern Time, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. By April 30, 2026, FDA will select and notify persons who request to present prepared public comment if they are selected for presentation during the workshop. Any presentation materials must then be emailed to GDUFARegulatoryScience@fda.hhs.gov no later than May 20, 2026, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. The link to the streaming webcast of the workshop on June 8, 2026 (Day 1 of the workshop), is: <https://teams.microsoft.com/meet/29276529473988?p=3uD9Z7KE>. The link to the streaming webcast of the workshop on June 9, 2026 (Day 2 of the workshop), is: <https://teams.microsoft.com/meet/29105893294615?p=fZ9hG2BU>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a video recording and audio transcript of the public workshop are available, they will be accessible at <https://www.regulations.gov> or via the Science & Research FDA website accessible at <https://www.fda.gov/drugs/generic-drugs/science-research>. They may also be available for viewing at the

¹ The GDUFA III commitment letter is available at <https://www.fda.gov/media/153631/download>.

Dockets Management Staff (see ADDRESSES).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-03961 Filed 2-26-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915-0151—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 30, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915-0151—Revision.

Abstract: The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program (CBDPP) under Part F of the Ryan White

HIV/AIDS Program (RWHAP) offer funding to accredited dental education programs to support the education and training of oral health providers in HIV oral health care and reimbursement for the provision of oral health services for people eligible for the RWHAP. Institutions eligible for the RWHAP DRP and CBDPP are accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency. The RWHAP DRP Application for the Notice of Funding Opportunity includes the Dental Services Report (DSR) that applicants use to apply for funding of non-reimbursed costs incurred in providing oral health care to clients with HIV and to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff-111(b)). The DSR is also used by CBDPP recipients to report on services rendered, clients served, and partnerships as an annual requirement. The DSR collects data on program information, client demographics, oral health services, funding, and training. It also requests applicants and recipients provide a narrative description of the services offered, the types of facilities available, and their linkage and collaboration with community-based oral health service providers.

Beginning with the 2022 DSR submission, the DSR website provided RWHAP DRP applicants and RWHAP CBDPP recipients an easily accessible and secure location to enter and submit their aggregate DSR data annually. All RWHAP DRP applicants and RWHAP CBDPP recipients will be authorized users of a web-based platform that allows users to easily navigate the site and enter their data. Users can see their report submission status and no longer need to email their dataset to HRSA. The implementation of the DSR website contributed to the overall decrease in burden hours. HRSA proposes minor modifications to the DSR data reporting tool:

- Remove the question regarding gender to align with administrative priorities.
- Add an "Unknown" response option for the "Sex at Birth" variable.
- Remove "People and Communities Disproportionately Impacted by HIV" from section 4.

A 60-day notice was published in the **Federal Register** on November 26, 2025,

vol. 90, No. 226; pp. 34332–33. There were no public comments.

Need and Proposed Use of the Information: The primary purpose of collecting this information annually is to verify applicant eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of CBDDP grant recipients. This information allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating persons with HIV, (2) the number and characteristics of clients who receive RWHAP supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to persons with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, community groups, and the public, information collected in the DSR is critical for HRSA and recipients to assess the status of existing HIV-related health service delivery systems. The information will provide the measurement data for the HRSA budget justifications on the following indicators: number of persons for whom a portion/percentage of their unreimbursed oral health costs were reimbursed and the number of providers trained through the RWHAP Part F Dental Reimbursement and Community-Based Partnership Programs.

Likely Respondents: Accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a general dental practice residency.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and use technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden