

Availability of Nonprescription Drugs; 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: Phong Pham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6122, Silver Spring, MD 20993–0002, 301–837–7656, Phong.Pham@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In connection with the **Federal Register** notice entitled “Increasing Access to Nonprescription Drugs; Request for Information,” published December 2, 2025 (90 FR 55316) (the December 2025 notice), we are announcing a public meeting to discuss topics related to increasing access to nonprescription drugs. This public meeting will be convened and supported by a cooperative agreement between FDA and the Duke-Margolis Institute for Health Policy. We also welcome any comments on specific topics covered at the public meeting or about increasing access to nonprescription drugs generally. If you submitted a comment to the December 2025 notice, you do not need to resubmit it here.

II. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the event website: <https://duke.is/p/4g3b>.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting in person must register by April 22, 2026, at 5 p.m. Eastern Time and receive registration confirmation. Early registration is recommended because seating is limited. Persons attending virtually must register by April 23, 2026, at 5 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please contact margolisevents@duke.edu no later than April 22, 2026, at 5 p.m. Eastern Time.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast via Zoom. The archived footage will be available at the event website: <https://duke.is/p/4g3b>.

Transcripts: A link to the transcript will be available on the internet at <https://duke.is/p/4g3b>.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07335 Filed 4–14–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3273]

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; 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 or the Agency) is announcing the following public meeting titled “Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.” The topic to be discussed is the financial transparency and efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.

DATES: The public meeting will be held on June 23, 2026, from 1:00 p.m. to 2:30 p.m. ET. Either electronic or written comments on this public meeting must be submitted by July 23, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held as a hybrid event with a virtual option via Microsoft Teams and an in-person option at the FDA White Oak Campus, Great Room, Section A. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security and parking information, please refer to <https://www.fda.gov/about-fda/visitor-information/public-meeting-information> and <https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map>.

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 July 23, 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 through the following:

• *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-2026-N-3273 for "Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; 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 9:00 a.m. and 4:00 p.m. ET, 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: Kichelle Joseph, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, Three White Flint North—11601 Landsdown St., North Bethesda, MD 20852, 301-796-7251, OFBABusinessManagementServices@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The meeting will include presentations from FDA on: (1) the five-year plan for the Prescription Drug User Fee Act (PDUFA) VII, Biosimilar User Fee Act (BsUFA) III, and Generic Drug User Fee Amendments (GDUFA) III; and (2) the Agency's progress in implementing resource capacity planning as part of fee setting and modernized time reporting. This meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year and can be found in the Commitment Letters listed below (sections II.B.2 of PDUFA VII (p. 58), III.B.2 of BsUFA III (p. 33), and VIII.D.3 of GDUFA III (p.40-41)).

PDUFA VII, BsUFA III, and GDUFA III represent the reauthorization of these user fee programs for FYs 2023–2027 as part of the FDA User Fee Reauthorization Act of 2022, which was signed by the President on September 30, 2022. The complete set of performance goals for each program is available at:

- PDUFA VII: <https://www.fda.gov/media/151712/download>
- BsUFA III: <https://www.fda.gov/media/152279/download>
- GDUFA III: <https://www.fda.gov/media/153631/download>

Each of these user fee programs' Commitment Letters included a set of commitments related to financial management to publish a five-year financial plan and update that plan annually, continue activities to mature FDA's resource capacity planning capability, and modernize time reporting practices. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA with the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VII, BsUFA III, and GDUFA III. These topics include the five-year financial plans for each of these programs and FDA's progress toward implementing resource capacity planning as part of fee setting and modernized time reporting.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://events.gcc.teams.microsoft.com/event/7727cea2-45bc-45b4-844a-1f86f2772529@7d2fdb41-339c-4257-87f2-a665730b31fc>. Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Persons interested in attending this public meeting must register by June 12, 2026, at 11:59 p.m. Eastern Time. If registration closes before the day of the public meeting, the Webinar Registration website will be updated.

If you need special accommodations due to a disability, please indicate this during registration or contact Kichelle Joseph at OFBABusinessManagementServices@fda.hhs.gov no later than June 12, 2026.

Streaming Webcast of the Public Meeting: This public meeting will be webcast. To register for the public

meeting and obtain the webcast information, please visit the following website: <https://events.gcc.teams.microsoft.com/event/7727cea2-45bc-45b4-844a-1f86f2772529@7d2fdb41-339c-4257-87f2-a665730b31fc>.

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 also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-07248 Filed 4-14-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-1255]

Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry.” The draft document provides recommendations for next-generation sequencing (NGS)-based methods used in nonclinical studies that will likely be needed to support initiation of clinical trials of investigational human genome editing (GE) products.

DATES: Submit either electronic or written comments on the draft guidance by July 14, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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-2026-D-1255 for “Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry.” Received comments 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>.

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You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, by emailing industry@biologics@fda.hhs.gov. The draft guidance may also be obtained by mail by calling CBER at 800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry.”

This draft guidance is intended for sponsors developing human gene therapy products involving GE technologies. Clinical development programs of human GE products should address both the risks associated with the gene therapy product itself as well as the additional risks associated with GE, including off-target editing and