4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2962]

Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment; 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 announcing the following public meeting entitled "Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment." The topic to be discussed is a hiring and retention assessment which was performed by an independent contractor.

DATES: The public meeting will be held in person and virtually on September 24, 2025, from 9 a.m. to 12 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by October 24, 2025. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting 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. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to https://www.dhs.gov/real-id/real-id-faqs. 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. Any changes to the public meeting location and remote information, as appropriate, will be posted to https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-

fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment 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 October 24, 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-2962 for "Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment; 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: Thamar Bailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32 Rm. 4103, Silver Spring, MD 20993-0002, 301-796-6645, CDERProgramEvaluation@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to meet performance commitments included in the Prescription Drug User Fee Act (PDUFA VII) and the Biosimilar User Fee Amendments (BsUFA III). These user fee programs were reauthorized for fiscal years 2023–2027 as part of the FDA User Fee Reauthorization Act of 2022 (Pub. L. 117-180) enacted on September 30, 2022. The complete set of performance goals for each program is available at:

- PDUFA VII program: *https://www.fda.gov/media/151712/download*
- BsUFA III program: *https://www.fda.gov/media/152279/download*

During the public meeting, FDA will share high-level findings from a recently completed assessment of FDA's hiring and retention of staff for the human drug review program. This assessment was conducted by a qualified, independent contractor with expertise in assessing Human Resource (HR) and Human Capital (HC) operations as agreed to in the PDUFA VII and BsUFA III commitment letters. Previously, as part of PDUFA VI and BsUFA II, independent contractors conducted a series of three assessments that aimed to capture the status of FDA's HR

and HC operations, identify challenges, and provide actionable recommendations. The previous reports are available at:

- Initial assessment report: *https://www.fda.gov/media/108866/download*
- Interim assessment report: *https://www.fda.gov/media/138662/download*
- Final assessment report: *https://www.fda.gov/media/154873/download*

The initial assessment served as a baseline, evaluated the state of FDA human resource operations, identified root causes of challenges, and provided recommendations related to recruitment and hiring. Unlike the subsequent evaluations, the initial assessment did not evaluate employee retention efforts. The interim and final assessments documented progress from the previous assessment(s) related to recommendations from the initial assessment, program milestones, metrics, and other aggregated feedback from internal HR/HC customers and participants and provided additional recommendations. The current assessment builds upon the findings from the three previous assessments with a focus on changes that have improved FDA's hiring and retention outcomes and challenges that remain. The current assessment also expands beyond the scope of the previous assessments to include the pre-employment onboarding process. This assessment report includes metrics related to recruiting and retention in the human drug review program, including specific targeted scientific disciplines, attrition, and utilization of pay authorities. The report also includes the contractor's findings and recommendations on further enhancements to hiring and retention of staff for the human drug review program. To view the assessment report, please visit: https://www.fda.gov/media/188083.

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to hiring and retention in the FDA human drug review program. The independent contractor will present their findings and recommendations that are outlined in the hiring and retention assessment report, and FDA will provide its perspective on the

independent contractor's findings and recommendations. To view the assessment report, please visit: https://www.fda.gov/media/188083.

III. Participating in the Public Meeting

Registration: To register for this hybrid public meeting, please visit the following website: https://FDAPublicMeeting_PDUFAVII_BsUFAIII_HiringandRetention.eventbrite.com. Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending the public meeting must register by September 15, 2025, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Thamar Bailey, 301-796-6645, CDERProgramEvaluation@fda.hhs.gov no later than September 15, 2025, 11:59 p.m. Eastern Time.

Opportunity for Public Comment: During online registration, you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. 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 presentations and request time for a joint presentation. All requests to make oral presentations during the meeting must be received via registration by September 15, 11:59 p.m. Eastern Time. Onsite registration for public comments on the day of the public meeting will not be provided. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify

participants by September 17, 2025. If selected to present at the public comment session, any presentation materials must be emailed to CDERProgramEvaluation@fda.hhs.gov by September 19, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast to registered attendees. To view the webcast of this public meeting, please register at https://FDAPublicMeeting_PDUFAVII_BsUFAIII_HiringandRetention.eventbrite.com (see "Registration"). Please provide complete contact information for each attendee, including, name, title, affiliation, and email.

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/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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