discussion and question and answer session.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/industry/fda-public-workshop-future-needs-development-interchangeable-products-09192025.* Please indicate either in-person or virtual attendance and provide complete contact information for each attendee, including name 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. Persons interested in attending this public workshop must register by Friday, September 19, 2025, at 9 a.m. Eastern Time for in-person registration. Virtual attendees can register and join at any time through the conclusion of the meeting. Early registration for in-person attendance 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 workshop will be provided beginning at 8:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Ikenberry, 301–796–6893, *sarah.ikenberry@fda.hhs.gov* no later than September 12, 2025.

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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

Dated: August 12, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15572 Filed 8–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2786]

Biosimilar User Fee Act III Regulatory Science Program Interim Public Meeting; Public Meeting; Interim Report; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Biosimilar User Fee Act (BsUFA) III Regulatory Science Program Interim Public Meeting'' and the availability of the report entitled ''BsUFA III Regulatory Science Pilot Program Interim Report.'' The purpose of the public meeting is to review the progress of the BsUFA III Regulatory Science Program aims, or demonstration projects, and to solicit input on future research priorities. Under the BsUFA reauthorization commitment letter for fiscal years (FYs) 2023 through 2027 (BsUFA III), FDA committed to piloting a regulatory science program to facilitate biosimilar and interchangeable product development that focuses on: (1) advancing the development of interchangeable products; and (2) improving the efficiency of biosimilar product development. The purpose of the interim progress report is to provide a summary of activities that established the pilot program, an overview of research progress, and a brief discussion of future directions.

DATES: The hybrid public meeting will be held on September 18, 2025, from 9 a.m. to 3 p.m. Eastern Time, and will take place in person and virtually. Either electronic or written comments on this public meeting and report must be submitted by October 18, 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. In-person 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.*

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 October 18, 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–2786 for ''Biosimilar User Fee Act III Regulatory Science Program

Interim Public Meeting; Public Meeting; Interim Report; Availability; 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: Sarah Ikenberry, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1128, Silver Spring, MD 20993–0002, 301–796–6893, *BsUFARegSciProgram@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under BsUFA III, FDA committed to piloting a regulatory science program to facilitate biosimilar and interchangeable product development that focuses on: (1) advancing the development of interchangeable products; and (2) improving the efficiency of biosimilar product development. FDA also committed to publish an interim progress report and hold an interim public meeting by October 31, 2025, approximately midway through the pilot program.

FDA is hosting a hybrid public meeting on September 18, 2025, to meet the BsUFA III commitment to review the progress of the pilot program aims or demonstration projects, and to solicit input on future research priorities. FDA has published the interim progress report entitled ''BsUFA III Regulatory Science Pilot Program Interim Report'' at *https://www.fda.gov/media/187445/download?attachment;* this report provides a summary of activities that established the pilot program, an overview of research progress, and a brief discussion of future directions.

II. Topics for Discussion at the Public Meeting

In general, the public meeting's format will include presentations by FDA and other interested parties, including scientific and academic experts participating in the BsUFA Regulatory Science pilot program and biosimilar industry representatives. The agenda includes an overview of the pilot program, awardee presentations on the progress of their research, lessons learned, and the role of regulatory science in biosimilar development. A draft agenda and other background information for the public is available at: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025.* Please indicate either in-person or virtual attendance and provide complete contact information for each attendee, including name 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. Persons interested in attending this public meeting must register by Thursday, September 18, 2025, at 9 a.m. Eastern Time for in-person registration. Virtual attendees can register and join at any time through the conclusion of the meeting. Early registration for in-person attendance 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 8:30 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Ikenberry, 301–796–6893, *BsUFARegSciProgram@fda.hhs.gov,* no later than September 11, 2025.

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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

Dated: August 12, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15571 Filed 8–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Infant-Toddler Court Program—National Resource Center

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA is providing additional award funds of $1,750,000 in federal fiscal year (FY) 2025 to ZERO TO THREE National Center for Infant, Toddler and Families, Inc., the current recipient of the Infant-Toddler Court Program (ITCP)—National Resource Center (NRC) cooperative agreement (HRSA–22–074), to support the continuation of existing activities, using the Infant Toddler Court (ITC) approach, to improve child welfare and early childhood systems and advance early developmental health and well-being. The supplemental funding would provide financial and technical support