U.S. FOOD & DRUG ADMINISTRATION

April 15, 2025

Justin Davis
Regulatory Affairs, U.S. Representative
LumiraDx UK Ltd.
Roche House Charles Avenue
Burgess Hill, England, RH15 9RY
Re: Revocation of EUA202584

Dear Justin Davis:
This letter is in response to the request from LumiraDx UK Ltd., in an email dated November 8, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete issued on October 14, 2020, revised and reissued on February 9, 2021, March 29, 2021, November 30, 2021, and February 18, 2022, and amended on March 22, 2021, April 13, 2021, September 23, 2021, April 25, 2022, August 17, 2022, September 15, 2022, February 22, 2023, and July 10, 2023. LumiraDx UK Ltd. indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable LumiraDx SARS CoV-2 RNA STAR Complete reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because LumiraDx UK Ltd. has requested that FDA revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202584 for the LumiraDx SARS CoV-2 RNA STAR Complete, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LumiraDx SARS CoV-2 RNA STAR Complete is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Technical Correction June 26, 2025: Edit to correct the date the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete was originally issued.

Dated: August 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15556 Filed 8–14–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2787]

Advancing the Development of Interchangeable Products: Identifying Future Needs; 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, the Agency, or we) is announcing the following public workshop entitled ''Advancing the Development of Interchangeable Products: Identifying Future Needs.'' The purpose of the public workshop is to address a commitment FDA made in the Biosimilar User Fee Act (BsUFA) reauthorization commitment letter for

fiscal years (FYs) 2023 through 2027 (BsUFA III) to hold a scientific workshop to discuss and identify future needs (*e.g.,* guidance, research) that, when addressed, may help further advance the development of interchangeable biosimilar products.

DATES: The hybrid public workshop will be held on September 19, 2025, from 9 a.m. to 1 p.m. Eastern Time, and will take place in person and virtually. Either electronic or written comments on this public workshop must be submitted by October 19, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop 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 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.*

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 19, 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–2787 for ''Advancing the Development of Interchangeable Products: Identifying Future Needs; 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: 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, *sarah.ikenberry@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is hosting a hybrid public workshop entitled ''Advancing the Development of Interchangeable Products: Identifying Future Needs,'' in accordance with the commitment in section II.D.3 of the BsUFA III commitment letter. The purpose of the public workshop is to seek stakeholder input on potential areas that need to be addressed to facilitate the development of interchangeable biosimilar products. Input received during the workshop will inform the development of a draft strategy document that outlines specific actions FDA will take to facilitate the development of interchangeable biosimilar products and that FDA will publish, for public input, within 12 months following the workshop.

II. Topics for Discussion at the Public Workshop

FDA and industry stakeholders invited by FDA will provide perspectives on future needs for the development of interchangeable biosimilar products. Additionally, FDA subject matter experts will discuss product quality considerations for biosimilars (including interchangeable biosimilars) and considerations around interchangeability from the perspective of user interface and human factor aspects related to delivery devices as well as other considerations around interchangeability of biological products. Following speaker presentations, presenters will participate in a moderated panel

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.

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- 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'').

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Submit written/paper submissions as follows:

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- 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