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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-3623]

Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development -- Leveraging Rare Disease Frameworks; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public workshop entitled "Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development -- Leveraging Rare Disease Frameworks." The aim of the public workshop is to discuss common challenges in neonatal and rare disease product development and identify opportunities to leverage rare disease product development frameworks in the neonatal product development space.

DATES: The public workshop will be held on Wednesday, December 10, 2025, 1:00 p.m. - 5:00 p.m. Eastern Time, and Thursday, December 11, 2025, from 8:30 a.m. until 4:00 p.m. Eastern Time. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop on December 10 and 11, 2025, will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Additionally, the meeting will be streamed online on both dates. Entrance for in-person registered 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 and https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, the Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7495, OPT@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Since 2014, FDA has hosted an annual public workshop focused on Advancing the Development of Pediatric Therapeutics (ADEPT). The ADEPT Workshops offer opportunities for stakeholders to meet to discuss challenging scientific issues related to pediatric product development and pediatric regulatory science. The primary aims of ADEPT Workshops are to:

- Discuss advancements in pediatric therapeutics development;
- Identify gaps in current knowledge and explore innovative approaches to address those gaps; and
- Provide a platform for open dialogue between regulators, industry, academia, and patient organizations.

II. Topics for Discussion at the Public Workshop

The specific topics for discussion at this workshop include, but are not limited to, the following:

- identifying common challenges in neonatal and rare disease product development;
- discussing ethical considerations relevant to neonatal and rare disease product development;
- identifying opportunities to leverage rare disease tools and strategies for neonatal conditions; and
- discussing the regulatory landscape of rare disease programs/resources and their application to neonatal conditions.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-10-addressing-challenges-neonatal-product. Please provide complete contact information for each attendee, including name, email address, and affiliation.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop in-person must register by December 9, 2025, at 12:00 p.m. Eastern Time; virtual attendees may register by December 10, 2025, at 12:00 p.m., Eastern Time. 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 first day of the public workshop (December 10, 2025) will be provided beginning at 11:00 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 OPT@fda.hhs.gov no later than November 26, 2025.

If you have never attended a Zoom event before, test your connection at https://zoom.us/test. 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 transcript of the public workshop is available, it will be accessible on the workshop website: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-10-addressing-challenges-neonatal-product.

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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