eligible clinicians, third-party intermediaries, Medicare beneficiaries, and any other audiences that would support the Agency in improving MIPS or the Quality Payment Program. The specific collections we intend to conduct are: Human Centered Design (HCD) User Testing Volunteer Sign-Up Survey; HCD User Satisfaction, Product Usage, and Benchmarking Surveys; and Physician Compare (and/or successor website) User Testing. *Form Number:* CMS–10695 (OMB control number: 0938–1399); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and Individuals; *Number of Respondents:* 630,300; *Total Annual Responses:* 630,300; *Total Annual Hours:* 61,035. (For policy questions regarding this collection, contact Renee O'Neill at 410–786–8821.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0001]

Enhancing Diversity in Therapeutics Development for Pediatric Patients; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Enhancing Diversity in Therapeutics Development for Pediatric Patients.'' The aim of the public workshop is to explore strategies to increase the enrollment of historically underrepresented populations in pediatric clinical trials and to help improve the strength and generalizability of the evidence for the intended use population.

DATES: The public workshop will be held on September 6, 2024, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop 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. Entrance for the 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*. The workshop will also be streamed online.

FOR FURTHER INFORMATION CONTACT: Julie Levin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6481, Silver Spring, MD 20993, 202–567–7565, or *ONDPublicMTGSupport@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trials in children are essential for obtaining data on the safety and effectiveness of medical products in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective for their intended uses in children. In some therapeutic areas, participation in clinical trials may be an important component of a participant's clinical care. Pediatric drug development programs should consider the clinical and demographic factors that impact the generalizability of study results with respect to the patient population that will use the product once it is approved.

II. Topics for Discussion at the Public Workshop

FDA, in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is convening a 1-day workshop to explore strategies for enrolling historically underrepresented populations in pediatric clinical trials. The specific topics to be covered include, but are not limited to, the following:

- Understanding the current state and challenges of pediatric clinical trial participation;
- Understanding metrics for assessing representative clinical study enrollment, including considerations of disease prevalence and incidence across subgroups of the pediatric population; and
- Discussing key elements of a strategy to include a more representative population, including trial design and methodological considerations, community engagement, recruitment and retention practices, and other related topics.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/drugs/news-events-human-drugs/adept-9-public-workshop-enhancing-diversity-therapeutics-development-pediatric-patients-09062024*. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

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 August 23, 2024, at 5 p.m. Eastern Time; virtual attendees may register by September 6, 2024, at 9 a.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 workshop will be provided beginning at 8:15 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 Julie Levin at 202–567–7565 or *ONDPublicMTGSupport@fda.hhs.gov* no later than August 16, 2024.

Streaming Webcast of the Public Workshop: This public workshop will also be streamed virtually via Zoom. A link will be provided via email to registered participants. 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.

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

Dated: July 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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