DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0001]

Advancing the Development of Pediatric Therapeutics on Drug Dosing in Pediatric Patients With Renal Impairment; 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 “Advancing the Development of Pediatric Therapeutics (ADEPT 8) on Drug Dosing in Pediatric Patients With Renal Impairment.” The purpose of the public workshop is to discuss the current landscape of drug dosing in pediatric patients with renal impairment, understand the gaps in knowledge, and consider innovative approaches to improve the current paradigm for dosing in pediatric patients with renal impairment.

DATES:  The public workshop will be held on November 30, 2023, and December 1, 2023, from 9 a.m. to 5 p.m. eastern time each day. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES:  The public workshop will be held at the FDA White Oak Campus Great Room and online. 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.

FOR FURTHER INFORMATION CONTACT:  Julie Levin, Office of New Drugs Public Meeting Support, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6481, Silver Spring, MD 20993-0002, 202-567-7565, ONDPublicMTGSupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background
The pharmacokinetics of drugs excreted by the kidneys may be altered by renal (kidney) impairment, requiring dosing adjustments. However, the majority of drugs that are predominantly renally excreted and have dosage recommendations for adults with renal impairment lack dose adjustment recommendations for pediatric patients with renal impairment. This is largely due to the lack of generation of pharmacokinetic data in pediatric patients with renal impairment, which is attributable to both the ethical and the practical limitations of conducting dedicated renal impairment studies in pediatric patients, as well as the exclusion of pediatric patients with renal impairment from most clinical efficacy and safety studies. For drugs that are renally cleared, exposures can be impacted by both the maturation of kidney function and the renal impairment due to kidney disease.

II. Topics for Discussion at the Public Workshop

The main objective of the “Advancing the Development of Pediatric Therapeutics (ADEPT 8) on Drug Dosing in Pediatric Patients With Renal Impairment” workshop is to discuss current approaches to classifying renal impairment in the pediatric population, identify data gaps, and explore scientifically supported approaches and methods for providing information on dosing adjustment. The workshop will specifically focus on measurements of renal function, extrapolation of adult data, and approaches to generating clinical trial data to assess the impact of renal impairment on the pharmacokinetics of drugs in pediatric patients. In addition, the workshop will allow for an open dialogue around the use of these approaches among regulators, industry, academia, and patient organizations.

III. Participating in the Public Workshop

**Registration:** To register for the public workshop, please visit the following website: https://www.eventbrite.com/e/adept-8-pediatric-renal-impairment-workshop-tickets-687423571407. 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 must register by November 15, 2023, 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 you need special accommodations due to a disability, please contact Julie Levin at ONDPublicMTGSupport@fda.hhs.gov no later than November 15, 2023.

*Streaming Webcast of the Public Workshop:* This public workshop will also be via Zoom. A link will be provided via email to registered participants. If you have never attended a Zoom event before, test your internet connection by joining a test meeting at https://zoom.us/test.

FDA has verified the website addresses in this document, as of the date this document is published in the *Federal Register*, but websites are subject to change over time.

*Transcripts:* Please be advised that when a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Dated:** September 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*