FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

November 13, 2025

FINAL MEETING AGENDA

The committee will meet to discuss pediatric focused post-market safety reviews as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109), the Pediatric Research Equity Act of 2003 (Pub. L. 108-155), and the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110-85, title III). The objective of the meeting is for the FDA to provide a forum for discussion about post-marketing pediatric-focused safety reviews completed by the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

10:00 a.m. **Call to Order and Introduction of the Committee**
Gwenyth Fischer, MD
Chairperson, PAC
Associate Professor of Pediatric Critical Care
University of Minnesota, College of Medicine

Conflict of Interest Statement
Shivana Srivastava, Designated Federal Officer
Office of Pediatric Therapeutics (OPT)
Office of the Chief Medical Officer (OCMO)
OC, FDA

FDA Opening Remarks
Prabha Viswanathan, MD, FAAP
Deputy Director
OPT, OCMO, OC, FDA

10:20 a.m. **FDA Pediatric Safety and Monitoring Framework Presentation and Q&A**
Mohamed Mohamoud, PharmD, MPH
Senior Clinical Analyst
OPT, OCMO, OC, FDA

11:00 a.m. **PAC Committee Discussion on Non-Voting Question**

12:15 p.m. **Lunch**

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1:15 p.m. **Open Public Hearing**
Gwenyth Fischer, MD

2:15 p.m. **Listing of products evaluated in the pediatric-focused post-market safety reviews completed by the Center for Devices and Radiological Health (CDRH)**
George Van Hare, MD
Medical Officer
Office of Cardiovascular Devices
CDRH, FDA
Clarifying Questions, Committee Discussion and Vote

2:45 p.m. **Listing of products evaluated in the pediatric-focused post-market safety reviews completed by the Center for Biologics Evaluation and Research (CBER)**
Craig Zinderman, MD, MPH
Associate Director for Medical Policy
Office of Biostatistics and Pharmacovigilance
CBER, FDA
Clarifying Questions, Committee Discussion and Vote

3:15 p.m. **Listing of products evaluated in the pediatric-focused post-market safety reviews completed by the Center for Drug Evaluation and Research (CDER)**
Ivone Kim, MD
Senior Medical Officer
Office of Surveillance and Epidemiology
CDER, FDA
Clarifying Questions, Committee Discussion and Vote

4:00 p.m. **Closing Remarks and Adjournment**
Gwenyth Fischer, MD