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

Pediatric Advisory Committee (PAC)

July 9, 2025

FINAL MEETING AGENDA

The committee will meet to discuss pediatric focused postmarket 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**
Gwenyth Fischer, MD
Chairperson, Pediatric Advisory Committee (PAC)
Associate Professor of Pediatric Critical Care
University of Minnesota, College of Medicine

Introduction of the Committee
Gwenyth Fischer, MD
Chairperson, PAC

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
Dionna Green, MD, FCP
Director
OPT, OCMO, OC, FDA

10:30 a.m. **Open Public Hearing**
Gwenyth Fischer, MD
Chairperson, PAC

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10:45 a.m. **Listing of products evaluated in the pediatric-focused postmarket safety reviews completed by the Center for Devices and Radiological Health (CDRH)**
Scott A. Colburn, MS, BSN, RN
Director
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation
CDRH, FDA

Clarifying Questions
Committee Discussion and Vote

11:15 p.m. **Listing of products evaluated in the pediatric-focused postmarket 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

12:30 p.m. **Lunch**

1:30 p.m. **Listing of products evaluated in the pediatric-focused postmarket 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

2:30 p.m. **Closing Remarks and Adjournment**
Gwenyth Fischer, MD
Chairperson, PAC