

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

September 18, 2024

DRAFT MEETING AGENDA

The committee will meet to discuss post-marketing pediatric-focused 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 41 post-marketing pediatric-focused safety reviews completed by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH).

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| 10:00 a.m. | Call to Order and Introduction of the Committee | Gwenyth Fischer, MD
Chairperson, Pediatric Advisory Committee (PAC)
Associate Professor of Pediatric Critical Care
University of Minnesota, College of Medicine |
| 10:10 a.m. | Introduction of FDA Representatives | Shivana Srivastava, RN, MS, PMP
Designated Federal Officer, PAC
Office of Pediatric Therapeutics (OPT)
Office of Clinical Policy and Programs (OCPP)
Food and Drug Administration (FDA) |
| 10:15 a.m. | Conflict of Interest Statement | Shivana Srivastava, RN, MS, PMP
Designated Federal Officer, PAC
OPT, OCPP, OC, FDA |
| 10:20 a.m. | FDA Opening Remarks | Dionna Green, MD, FCP
Director
OPT, OCPP, OC, FDA |
| 10:30 a.m. | FDA Background Presentation <ul style="list-style-type: none">• Pediatric-Focused Postmarket Safety Reviews for the Pediatric Advisory Committee | Mohamed Mohamoud, Pharm.D. MPH
Senior Clinical Analyst
OPT, OCPP, OC, FDA |
| 11:00 a.m. | OPEN PUBLIC HEARING | Gwenyth Fischer, MD
Chairperson, PAC |
| 12:00 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 |
| | <i>Clarifying Questions</i> | |
| 12:45 p.m. | LUNCH | |

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DRAFT MEETING AGENDA (cont.)

1:30 p.m. *Committee Discussion and Vote (CDER)*

2:30 p.m. Listing of products evaluated in the pediatric-focused postmarket safety reviews completed by the Center for Devices and Radiological Health (CDRH)

Vasum Peiris MD, MPH, FAAP, FACC, FASE
Associate Director and Chief Medical Officer for Pediatrics and Special Populations
CDRH, FDA

Clarifying Questions

Committee Discussion and Vote

3:15 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

4:00 p.m. **ADJOURNMENT**

Gwenyth Fischer, MD
Chairperson, PAC