

# FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

## *Pediatric Advisory Committee (PAC)*

September 18, 2024

### FINAL MEETING AGENDA

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

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***Pediatric Advisory Committee (PAC)***

September 19, 2023

**DRAFT MEETING AGENDA (cont.)**

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12:45 p.m. **LUNCH**

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**  
Chief Medical Officer and Director  
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