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).

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 • Pediatric-Focused Postmarket Safety Reviews for the Pediatric Advisory Committee *Clarifying Questions*	**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) *Clarifying Questions*	**Ivone Kim, MD** Senior Medical Officer Office of Surveillance and Epidemiology CDER, FDA

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DRAFT MEETING AGENDA (cont.)

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