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

***Pediatric Advisory Committee (PAC)***
September 16, 2026

**MEETING AGENDA**

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*The committee will meet to discuss postmarket 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 26 postmarket 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 | **Premchand Anne, MD**<br>Chairperson, Pediatric Advisory Committee (PAC)<br>Director, Division of Pediatric Cardiology<br>Henry Ford St. John Children's Hospital<br>Detroit, Michigan |
| 10:10 a.m. | Introduction of FDA Representatives | **Shivana Srivastava, RN, MS, PMP**<br>Designated Federal Officer, PAC<br>Office of Pediatric Therapeutics (OPT)<br>Office of Chief Medical Officer (OCMO)<br>Office of the Commissioner (OC)<br>Food and Drug Administration (FDA) |
| 10:15 a.m. | Conflict of Interest Statement | **Shivana Srivastava, RN, MS, PMP**<br>Designated Federal Officer, PAC<br>OPT, OCMO, OC, FDA |
| 10:20 a.m. | FDA Opening Remarks | **An Massaro, MD**<br>Director<br>OPT, OCMO, OC, FDA |
| 10:30 a.m. | Overview of Adverse Event Reporting to FDA: A CDER Perspective<br><br>*Questions* | **CDR Quocbao Pham, Pharm.D., MBA, BCPS**<br>Regulatory Scientist<br>Office of Surveillance and Epidemiology<br>Center for Drug Evaluation and Research (CDER), FDA |
| 11:00 a.m. | **OPEN PUBLIC HEARING** | **Premchand Anne, MD**<br>Chairperson, PAC |
| 12:00 p.m. | **LUNCH** | |

## MEETING AGENDA (cont.)

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| 1:00 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**<br>Senior Medical Officer<br>Office of Surveillance and Epidemiology<br>CDER, FDA |
| | *Clarifying Questions* | |
| | *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) | **Douglas Silverstein, MD**<br>Medical Officer<br>Clinical and Scientific Policy Staff<br>CDRH, FDA |
| | *Clarifying Questions* | |
| | *Committee Discussion and Vote (CDRH)* | |
| 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) | **Brendan Day, MD, MPH**<br>Acting Director, Division of Pharmacovigilance,<br>Office of Biostatistics and Pharmacovigilance<br>CBER, FDA |
| | *Clarifying Questions* | |
| | *Committee Discussion and Vote (CBER)* | |
| 4:00 p.m. | **ADJOURNMENT** | **Premchand Anne, MD**<br>Chairperson, PAC |