

Pediatric Advisory Committee Meeting
Tuesday, September 12, 2017
[Hilton Washington DC/Rockville Hotel & Executive Meeting Center](#)
 1750 Rockville Pike, Rockville, MD 20852
FINAL AGENDA

8:30a.m.	Welcome and Introductory Remarks for Day Pediatric Advisory Committee Meeting	Kelly Wade, MD, PhD <i>Acting</i> Chair of the Pediatric Advisory Committee Meeting Attending Neonatology Department of Pediatrics Children’s Hospital of Philadelphia Philadelphia, PA 19107
8:35 a.m.	Opening Statement	Marieann R. Brill, MBA, RAC, MT (ASCP) Designated Federal Official (DFO), PAC Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:40 a.m.	Introduction and Review of Agenda	Robert “Skip” Nelson, MD, PhD Deputy Director, and Senior Pediatric Ethicist, Office of Pediatric Therapeutics, Office of the Commissioner, U.S. Food and Drug Administration Office of the Commissioner (OC), FDA
8:45 a.m.	State of the PAC <i>Questions and Answers</i>	Robert “Skip” Nelson, MD, PhD
9:15 a.m.	Open Public Hearing	Marieann R. Brill, MBA, RAC, MT (ASCP) DFO
	Center for Drug Evaluation and Research (CDER) <u>Standard Review of Adverse Event Presentations</u>	
9:30 a.m.	Abilify (aripiprazole) <i>Questions and Recommendations</i>	Carolyn Yancey, MD, Medical Officer, Division of Pediatric and Maternal Health, (DPMH), OND, ODE IV, CDER, FDA
10:30 a.m.	Keppra and Keppra XR (levetiracetam) <i>Questions and Recommendations</i>	Yeruk (Lily) Mulugeta, Pharm.D., DPMH, OND, ODE IV, CDER, FDA
10:45 a.m.	BREAK	
	Center for Devices and Radiological Health (CDRH) <u>Standard Review of Adverse Event Presentations</u>	

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11:05 p.m.	CONTEGRA Pulmonary Valved Conduit <i>Questions and Recommendations</i>	Dora Vega, MD, PhD Epidemiology Evaluation and Research Branch II, Division of Epidemiology, Office of Surveillance and Biometrics, CDRH, FDA
11:25 p.m.	Enterra™ Therapy System <i>Questions and Recommendations</i>	Dora Vega, MD, PhD
11:45 p.m.	Elana Surgical Kit (HUD) <i>Questions and Recommendations</i>	Dora Vega, MD, PhD
11:50 p.m.	Pleximmune <i>Questions and Recommendations</i>	Courtney Lias, PhD, Director for the Division of Chemistry and Toxicology Device, Office of In Vitro Diagnostics and Radiological Devices, CDRH, FDA
11:55 a.m.	Berlin Heart® EXCOR® Pediatric Ventricular Assist Device (VAD)	Vasum Peiris, MD, MPH, FAAP, FACC, FASE, Chief Medical Officer, Office of the Center Director, CDRH
12:00 p.m.	Kidnet Trajectory: Where Have We Been? Where Should We Go?	Ann McMahon, MD, MS Deputy Director of Science, Director of the Kidnet Project, Office of Pediatric Therapeutics, Office of the Commissioner (OC), FDA
12:45 p.m.	Final Remarks and Adjournment	Kelly Wade, MD, PhD <i>Acting</i> Chair of Pediatric Advisory Committee (PAC)