

Pediatric Advisory Committee Meeting
Monday & Tuesday, September 11-12, 2017
[Hilton Hotel & Executive Meeting Center](#)
 1750 Rockville Pike, Rockville, MD 20852

DRAFT AGENDA (8/18/2017 4:41 PM)

8:30a.m.	Welcome and Introductory Remarks for Day Pediatric Advisory Committee Meeting	Mark Hudak, MD Chair of Pediatric Advisory Committee (PAC) Assistant Dean of Managed Care for the University of Florida University of Florida College of Medicine - Jacksonville Assistant Medical Director Neonatal Intensive Care Unit University of Florida Health Science Center/Jacksonville
8:35 a.m.	Opening Statement	Marieann R. Brill, MBA 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, Office of Pediatric Therapeutics 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, 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, DPMH, CDER, FDA
10:00 a.m.	Keppra and Keppra XR (levetiracetam) <i>Questions and Recommendations</i>	Lily (Yeruk) Mulugeta, MD, Medical Officer, DPMH, CDER, FDA
10:30 a.m.	BREAK	
10:45 a.m.	Kidnet Trajectory: Where Have We Been? Where Should We Go?	Ann McMahon, MD Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
11:15 p.m.	<u>CONTEGRA Pulmonary Valved Conduit</u> <i>Questions and Recommendations</i>	Dora Vega, MD Epidemiology Evaluation and Research Branch II, Division of Epidemiology, OSB, CDRH, FDA

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11:45 p.m.	<u>Enterra™ Therapy System</u> <i>Questions and Recommendations</i>	Dora Vega, MD
12:15 p.m.	<u>Pleximmune</u> <i>Questions and Recommendations</i>	Dora Vega, MD
12:25 p.m.	<u>Elana Surgical Kit (HUD)</u> <i>Questions and Recommendations</i>	Dora Vega, MD
12:45 p.m.	Final Remarks Adjournment	Mark Hudak, MD Chair of Pediatric Advisory Committee (PAC)