

Pediatric Advisory Committee Meeting
Tuesday, April 12, 2016
[DoubleTree by Hilton Hotel](#)
8120 Wisconsin Avenue
Bethesda, MD 20814
DRAFT AGENDA (v. 9.24)

8:00 a.m.	Welcome and Introductory Remarks	Mark Hudak, MD Chair of Pediatric Advisory Committee (PAC) Chief, Division of Neonatology University of Florida, College of Medicine Assistant Medical Director Neonatal Intensive Care Unit Wolfson Children’s Hospital Jacksonville, FL
8:10 a.m.	Introduction of New Designated Federal Official and Award Presentations	Robert “Skip” Nelson, MD, PhD Deputy Director, Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:20 a.m.	Opening Statement	Marieann R. Brill, MBA, RAC, MT (ASCP) Designated Federal Official, PAC Office of Pediatric Therapeutics(OPT) Office of the Commissioner (OC), FDA
8:30 a.m.	AAP Presentation Analgesic Development for Pediatric Patients	Chris Feudtner, MD, PhD, MPH, FAAP, Chair of the American Academy of Pediatrics (AAP) Section on Hospice and Palliative Medicine Sharon Hertz, MD Director, Division of Anesthesia, Analgesia and Addiction Products (DAAAP), Center for Drug Evaluation and Research (CDER). FDA
9:30 a.m.	Open Public Hearing	Mark Hudak, MD, Chair
10:30 a.m.	BREAK	

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<p>10:45 a.m.</p>	<p style="text-align: center;">Center for Biologics Evaluation and Research (CBER)</p> <p><u>Abbreviated Presentations</u> FluLaval Quadrivalent (Influenza Vaccine)</p> <p><i>Questions and Recommendations</i></p>	<p>LCDR Kenneth Quinto, MD, MPH OPT, OC, FDA</p>
<p>10:50 a.m.</p>	<p>FluLaval (Influenza Vaccine)</p> <p><i>Questions and Recommendations</i></p>	<p>LCDR Kenneth Quinto, MD, MPH</p>
<p>10:55 a.m.</p>	<p>Fluzone Quadrivalent (Influenza Vaccine)</p> <p><i>Questions and Recommendations</i></p>	<p>LCDR Kenneth Quinto, MD, MPH</p>
<p>11:00a.m.</p>	<p style="text-align: center;">Center for Drug Evaluation and Research (CDER)</p> <p><u>Abbreviated Presentation</u></p> <p>SKYLA (levonorgestrel-releasing intrauterine system)</p> <p><i>Questions and Recommendations</i></p>	<p>Judith U. Cope, MD, MPH OPT, OC, FDA</p>
<p>11:15 a.m.</p>	<p>Xeloda® (capecitabine)</p> <p><i>Questions and Recommendations</i></p>	<p>Judith U. Cope, MD, MPH</p>
<p>11:30.am.</p>	<p><u>Standard Review of Adverse Event Presentations</u></p> <p>MYCAMINE (micafungin sodium)</p> <p><i>Questions and Recommendations</i></p>	<p>LCDR Erica Radden, MD Division of Pediatric & Maternal Health (DPMH), Office of New Drugs (OND), CDER, FDA</p>
<p>12:00 p.m.</p>	<p>Noxafil® (posaconazole)</p> <p><i>Questions and Recommendations</i></p>	<p>Amy Taylor, MD, DPMH,OND, CDER, FDA</p>
<p>12:30 p.m.</p>	<p><u>WORKING LUNCH</u> TOPIC: Risk-based Assessment Proposal</p>	<p>LCDR Kenneth Quinto, MD, MPH OPT, OC, FDA</p>

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1:15 p.m.	Precedex™ (dexmedetomidine hydrochloride) <i>Questions and Recommendations</i>	Amy Taylor, MD, DPMH, OND, CDER, FDA
1:45 p.m.	Aciphex® Sprinkle™ (rabeprazole sodium) <i>Questions and Recommendations</i>	Amy Taylor, MD
2:15p.m.	Vyvanse® Capsules (lisdexamfetamine dimesylate) <i>Questions and Recommendations</i>	Mona Khurana, MD DPMH, OND, CDER, FDA
2:45 p.m.	BREAK	
3:00 p.m.	SYMBYAX (fluoxetine hydrochloride and olanzapine) <i>Questions and Recommendations</i>	Mona Khurana, MD
3:30 p.m.	Seroquel® (quetiapine fumarate) & Seroquel XR® (quetiapine fumarate extended-release) <i>Questions and Recommendations</i>	Donna Snyder, MD DPMH, OND, CDER, FDA
4:00 p.m.	Sabril® (vigabatrin) <i>Questions and Recommendations</i>	Donna Snyder, MD
4:30 p.m.	Center for Devices and Radiological Health (CDRH) <u>Annual Update of Post-Market HDE Reviews:</u> Medtronic Activa® Dystonia Therapy <i>Questions and Recommendations</i>	Courtney Millin, PhD Product Evaluation Branch III, Division of Postmarket Surveillance, Office of Surveillance and Biometrics (OSB), Center for Devices and Radiological Health (CDRH), FDA

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4:45 p.m.	Liposorber® LA-15 System <i>Questions and Recommendations</i>	Douglas Silverstein, MD, Medical Officer Renal Devices Branch, Division of Reproductive, Gastro-Renal and Urological Devices, Office of Device Evaluation (ODE), CDRH, FDA
5:00 p.m.	<u>Initial Post-Market HDE Review:</u> Impella® RP System <i>Questions and Recommendations</i>	John Laschinger, MD, Medical Officer Structural Heart Devices Branch, Division of Cardiovascular Devices ODE, CDRH, FDA
5:30 p.m.	Wrap-up and Adjournment	Mark Hudak, MD, Chair