

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

8:00 a.m.	<b>Welcome and Introductory Remarks</b>	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.	<b>Introduction of New Designated Federal Official and Award Presentations</b>	Robert “Skip” Nelson, MD, PhD Deputy Director, Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:15 a.m.	<b>Opening Statement</b>	Marieann R. Brill, MBA, RAC, MT (ASCP) Designated Federal Official, PAC Office of Pediatric Therapeutics(OPT) Office of the Commissioner (OC), FDA
8:20 a.m.	<b>Opioids and Children: Framework for Labeling Drugs to Promote Appropriate Treatment of Pain</b>  <b>Analgesic Development for Pediatric Patients</b>	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
9:22 a.m.	<b>Open Public Hearing</b>	Mark Hudak, MD, Chair

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<p><b>9:35 a.m.</b></p> <p><b>9:40 a.m.</b></p> <p><b>9:45 a.m.</b></p>	<p style="text-align: center;"><b>Center for Biologics Evaluation and Research (CBER)</b></p> <p><b><u>Abbreviated Presentations</u></b>  <b>FluLaval Quadrivalent (Influenza Vaccine)</b></p> <p><i>Questions and Recommendations</i></p> <p><b>FluLaval (Influenza Vaccine)</b></p> <p><i>Questions and Recommendations</i></p> <p><b>Fluzone Quadrivalent (Influenza Vaccine)</b></p> <p><i>Questions and Recommendations</i></p>	<p>LCDR Kenneth Quinto, MD, MPH OPT, OC, FDA</p> <p>LCDR Kenneth Quinto, MD, MPH</p> <p>LCDR Kenneth Quinto, MD, MPH</p>
<p><b>9:50 a.m.</b></p>	<p style="text-align: center;"><b>BREAK</b></p>	
<p><b>10:00a.m.</b></p> <p><b>10:20 a.m.</b></p>	<p style="text-align: center;"><b>Center for Drug Evaluation and Research (CDER)</b></p> <p><b><u>Abbreviated Presentation</u></b></p> <p><b>SKYLA (levonorgestrel-releasing intrauterine system)</b></p> <p><i>Questions and Recommendations</i></p> <p><b>Xeloda® (capecitabine)</b></p> <p><i>Questions and Recommendations</i></p>	<p>Judith U. Cope, MD, MPH OPT, OC, FDA</p> <p>Judith U. Cope, MD, MPH</p>
<p><b>10:30.am.</b></p> <p><b>10:50 a.m.</b></p>	<p><b><u>Standard Review of Adverse Event Presentations</u></b></p> <p><b>MYCAMINE (micafungin sodium)</b></p> <p><i>Questions and Recommendations</i></p> <p><b>Noxafil® (posaconazole)</b></p> <p><i>Questions and Recommendations</i></p>	<p>LCDR Erica Radden, MD Division of Pediatric &amp; Maternal Health (DPMH), Office of New Drugs (OND), CDER, FDA</p> <p>Amy Taylor, MD, DPMH, OND, CDER, FDA</p>

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<b>11:00 a.m.</b>	<p><b>Precedex™ (dexmedetomidine hydrochloride)</b></p> <p><i>Questions and Recommendations</i></p>	Amy Taylor, MD, DPMH, OND, CDER, FDA
<b>12:00 p.m.</b>	<p><b>Aciphex® Sprinkle™ (rabeprazole sodium)</b></p> <p><i>Questions and Recommendations</i></p>	Amy Taylor, MD
<b>12:30 p.m.</b>	<b>BREAK</b>	
<b>12:40 p.m.</b>	<p><b><u>WORKING LUNCH</u></b></p> <p><i>TOPIC:</i></p> <p><b>Risk-based Assessment Proposal</b></p> <p><i>Discussion</i></p>	LCDR Kenneth Quinto, MD, MPH OPT, OC, FDA
<b>1:40 p.m.</b>	<p><b>Vyvanse® Capsules (lisdexamfetamine dimesylate)</b></p> <p><i>Questions and Recommendations</i></p>	Mona Khurana, MD DPMH, OND, CDER, FDA
<b>2:35 p.m.</b>	<p><b>SYMBYAX (fluoxetine hydrochloride and olanzapine)</b></p> <p><i>Questions and Recommendations</i></p>	Mona Khurana, MD
<b>2:50 p.m.</b>	<p><b>Seroquel® (quetiapine fumarate) &amp; Seroquel XR® (quetiapine fumarate extended-release)</b></p> <p><i>Questions and Recommendations</i></p>	Donna Snyder, MD DPMH, OND, CDER, FDA
<b>3:20 p.m.</b>	<p><b>Sabril® (vigabatrin)</b></p> <p><i>Questions and Recommendations</i></p>	Donna Snyder, MD
<b>3:50 p.m.</b>	<p style="text-align: center;"><b>Center for Devices and Radiological Health (CDRH)</b></p> <p><b><u>Initial Post-Market HDE Review:</u></b></p> <p><b>Impella® RP System</b></p> <p><i>Questions and Recommendations</i></p>	John Laschinger, MD, Medical Officer Structural Heart Devices Branch, Division of Cardiovascular Devices

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4:20 p.m.	<p><b><u>Annual Update of Post-Market HDE Reviews:</u></b></p> <p><b>Medtronic Activa® Dystonia Therapy</b></p> <p><i>Questions and Recommendations</i></p>	<p>ODE, CDRH, FDA</p> <p>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</p>
4:40 p.m.	<p><b>Liposorber® LA-15 System</b></p> <p><i>Questions and Recommendations</i></p>	<p>Douglas Silverstein, MD,  Medical Officer  Renal Devices Branch, Division of  Reproductive, Gastro-Renal and  Urological Devices, Office of Device  Evaluation (ODE), CDRH, FDA</p>
5:15 p.m.	<p><b>Wrap-up and Adjournment</b></p>	<p>Mark Hudak, MD, Chair</p>