

**Pediatric Advisory Committee
Monday September 11, 2017
Hilton Washington DC/Rockville Hotel & Executive Meeting Center
1750 Rockville Pike, Rockville, MD, 20852**

DRAFT AGENDA

8:30 a.m.	Welcome and Introductions	Mark Hudak, MD Chair, Pediatric Advisory Committee Professor of Pediatrics University of Florida, College of Medicine
8:40 a.m.	Opening Statement	Marieann R. Brill, MBA Designated Federal Officer, PAC Office of Pediatric Therapeutics Office of the Commissioner (OC), United States Food and Drug Administration (FDA)
8:50 a.m.	Opening Remarks	John Alexander, MD, MPH Deputy Director Division of Pediatric and Maternal Health (DPMH) Center for Drug Evaluation and Research (CDER), FDA
8:55 a.m.	Taming Chronic Cough in the Peds World	John Oppenheimer, MD Chief of Allergy, Atlantic Health System Clinical Professor of Medicine UMDNJ-Rutgers Director of Clinical Research at Pulmonary and Allergy Associates
9:25 a.m.	Background on the Use of Opioids as Antitussives	Peter Starke, MD, FAAP Associate Director for Labeling Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) CDER, FDA
9:45 a.m.	Pediatric Outpatient Prescription Utilization of Opioid and Non-Opioid Containing Antitussives	Tracy Pham, Pharm.D. Division of Epidemiology II Office of Surveillance and Epidemiology (OSE), CDER, FDA
10:00 a.m.	Pediatric Cough & Cold Products: Analysis of American Association of Poison Control (AAPCC) Data, 2011-2016	Sara Karami, PhD Division of Epidemiology I OSE, CDER, FDA
10:15 a.m.	Additional Considerations in the Use of Opioids for Cough	Amy Taylor, MD, MHS Medical Officer, DPMH, CDER, FDA
10:25 a.m.	Industry Presentation Sovereign Pharmaceuticals, LLC	Leonard Lawrence Regulatory Affairs Sovereign Pharmaceuticals, LLC
10:50 a.m.	Break	

11:05 a.m.	Industry Presentation UCB Pharmaceuticals	Victor S. Sloan, MD, FACP, FACR Vice President/Development Strategy Lead Immunology Patient Value Unit UCB BIOSCIENCES Inc.
11:30 a.m.	Opioid Misuse and Opioid Use Disorders in Adolescents	Sharon Levy, MD, MPH Associate Professor of Pediatrics Harvard Medical School Director, Adolescent Substance Abuse Program Boston Children's Hospital
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Advisory Committee Question and Answer Period	Drs. Hudak and Alexander
2:30 p.m.	Statement of Questions for the Committee, Discussion, and Vote	Drs. Hudak and Alexander
4:00 pm	Adjourn for day	