Pediatric Advisory Committee Meeting
Monday & Tuesday, March 6 & 7, 2017
DoubleTree by Hilton Hotel
8727 Colesville Road
Silver Spring, MD 20910

AGENDA

8:30 a.m.	**Welcome and Introductory Remarks for Day 1 (MARCH 6) of the 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.	**Review of Agenda and Introduction of Dr. Susan McCune, the New Director of the Office of Pediatric Therapeutics**	Robert "Skip" Nelson, MD, PhD Deputy Director, Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:40 a.m.	**Opening Statement**	Marieann R. Brill, MBA Designated Federal Official, PAC Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:45 a.m.	**Open Public Hearing**	Marieann R. Brill, MBA Designated Federal Official, PAC
8:50 a.m. **9:01 a.m.**	**Pediatric Focused Safety Review Update-- Exjade® (deferasirox)**	Peter Waldron, MD, Division of Pharmacovigilance II, Office of Pharmacovigilance and Epidemiology, Center for Drug Evaluation and Research (CDER), FDA AND Kate Gelperin, MD, MPH, Medical Officer, Division of Epidemiology I, Office of Surveillance and Epidemiology, CDER, FDA

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10:06 a.m.	**Center for Drug Evaluation and Research (CDER)** **Standard Review of Adverse Event Presentations** **Kuvan (sapropterin dihydrochloride)** *Questions and Recommendations*	Jacqueline Spaulding, MD Division of Pediatric & Maternal Health, Office of New Drugs, CDER, FDA
10:30 a.m.	**BREAK**	
10:53 a.m.	**Nitropress® (sodium nitroprusside)** *Questions and Recommendations*	Lily (Yeruk) Mulugeta, Pharm.D Division of Pediatric & Maternal Health, Office of New Drugs, CDER, FDA
11:45 a.m.	**LUNCH**	
1:03 p.m.	**The Role of Pharmacogenomic Data in Pediatric Therapeutics**	Robert "Skip" Nelson, MD, PhD Deputy Director, Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
1:10 p.m.	**Pharmacogenomics in Pediatric Product Development and Labeling**	Dionna Green, MD, Medical Officer/Policy Lead Guidance and Policy Team, Office of Clinical Pharmacology, FDA
1:29 p.m.	**Case Studies in Pharmacogenetics**	Michael Pacanowski, Pharm.D, MPH Office of Clinical Pharmacology, Center for Drug Evaluation and Research, FDA
2:10 p.m.	**Analytical and Clinical Validation of Pharmacogenetic tests**	Kellie B. Kelm, PhD Chief, Cardio-Renal Diagnostic Devices Branch Division of Chemistry and Toxicology Devices

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		Office of In Vitro Diagnostic Devices and Radiological Health Center for Devices and Radiological Health, FDA
2:10 p.m.	**Clinical Implementation of Precision Therapeutics in Children**	J. Steven Leeder, PharmD, PhD, Director, Division of Clinical Pharmacology, Toxicology & Therapeutic Innovation Associate Chair-Research, Department of Pediatrics Deputy Director, Children's Research Institute Children's Mercy Kansas City Professor of Pediatrics and Pharmacology UMKC Schools of Medicine and Pharmacy
3:00 p.m.	**BREAK**	
3:20 p.m.	**Discussion**	Mark Hudak, MD Chair of Pediatric Advisory Committee
5:00 p.m.	**Summary and Wrap-up**	Robert "Skip" Nelson, MD, PhD Deputy Director, Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
5:15 p.m.	**Adjournment**	Mark Hudak, MD Chair, Pediatric Advisory Committee

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8:30 a.m.	**Welcome and Introductory Remarks for Day 2 (MARCH 7) of the 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.	**Introduction and Review of Agenda**	Robert "Skip" Nelson, MD, PhD Deputy Director, Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:40 a.m.	**Opening Statement**	Marieann R. Brill, MBA Designated Federal Official, PAC Office of Pediatric Therapeutics Office of the Commissioner (OC), FDA
8:50 a.m.	**Open Public Hearing**	Marieann R. Brill, MBA Designated Federal Official, PAC
	Center for Biologics Evaluation and Research (CBER) **Abbreviated Presentations**	
8:55 a.m.	**Novoeight® (turotocog alfa) Antihemophilic Factor (Recombinant)** *Questions and Recommendations*	LCDR Kenneth Quinto, MD, MPH Office of Pediatric Therapeutics, OC, FDA
9:08 a.m.	**RIXUBIS [Coagulation Factor IX (Recombinant)]** *Questions and Recommendations*	LCDR Kenneth Quinto, MD, MPH

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9:15 a.m.	**Initial Post-Market HDE Review** **Epicel ® (cultured epidermal autografts)** **HDE**	Meghna Alimchandani, MD, Chief, Pharmacovigilance Branch Division of Epidemiology Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research (CBER), FDA AND Nasrin Mirsaidi, MSN, RN Product Evaluation Branch II, Division of Postmarket Surveillance, Office of Surveillance and Biometrics (OSB), Center for Devices and Radiological Health (CDRH), FDA
	Center for Devices and Radiological Health (CDRH) **Annual Update of Post-Market HDE Reviews:**	
10:08 a.m.	**Medtronic Activa® Dystonia Therapy** *Questions and Recommendations*	Andrew Miller, MS, Adverse Event Analyst, PEB III, OSB, CDRH, FDA
10:35 a.m.	**Impella® RP System** *Questions and Recommendations*	George Aggrey, MD, MPH, Medical Officer, Epidemiology Evaluation and Research Branch I, Division of Epidemiology, OSB, CDRH, FDA
11:00 p.m.	**Liposorber® LA-15 System** *Questions and Recommendations*	Douglas Silverstein, MD, Medical Officer, Renal Devices Branch, Division of Reproductive, Gastro-Renal and Urological Devices, Office of Device Evaluation (ODE), CDRH, FDA
11:40 p.m.	**Adjournment**	Mark Hudak, MD Chair, Pediatric Advisory Committee