Pediatric Advisory Committee Meeting
March 23, 2018
US Food and Drug Administration (FDA) GREAT ROOM

DRAFT AGENDA

8:30 a.m.	**Welcome and Introductory Remarks for 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.	**Opening Statement**	**Marieann R. Brill, MBA** Designated Federal Official (DFO), PAC Office of Pediatric Therapeutics (OPT) Office of the Commissioner (OC), Office of Special Medical Programs (OSMP), FDA
8:40 a.m.	**Office of Pediatric Therapeutics Opening Remarks**	**Susan McCune, MD,** Director, OPT**,** OSMP, OC, FDA
8:50 a.m.	**Introduction with Updates on Agenda**	**Judith U. Cope, MD, MPH,** Safety Team Leader, OPT, OC, OSMP, OC, FDA
9:00 a.m.	**Open Public Hearing**	**Marieann R. Brill, MBA** DFO, PAC, OPT, OSMP, OC, FDA
10:00 a.m.	**Break**	
10:10 a.m.	**Update on the Safety of Long Acting Beta Agonists (LABA)**	**Robert Lim, MD,** Lead Medical Officer, Division of Pulmonary, Allergy, and Rheumatology Products, Office of Drug Evaluation II, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), FDA
10:20 a.m.	**Update on FDA approach to safety issue of gadolinium retention after administration of gadolinium-based contrast agents**	**Anthony Fotenos, MD**, **PhD**, Lead Medical Officer, Division of Medical Imaging, Office of Drug Evaluation IV, OND, CDER, FDA
10:40 a.m.	**Center for Drug Evaluation and Research (CDER)** **<u>Standard Review of Adverse Event Presentations</u>** **Lexapro™ (escitalopram oxalate)**	**CDR Courtney M. Suggs, PharmD, MPH** Office of Surveillance and Epidemiology, Division of Pharmacovigilance I (DPVI), OND, CDER, FDA

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11:00 a.m.	**Generic Drugs Topic:** **Drug-Ineffective Postmarketing Reports in Drug Safety Surveillance**	**Cindy Kortepeter, PharmD., Director, Division of Pharmacovigilance** Office of Pharmacovigilance and Epidemiology, DPVI, OND, CDER, FDA
11:15 a.m.	**Generic Drug Development and Safety Evaluation**	**Howard D. Chazin, MD, MBA** Director, Clinical Safety Surveillance Staff, Office of Generic Drugs, CDER, FDA
11:50 a.m.	**Lexapro™ (escitalopram oxalate)** *Questions and Recommendations* **Generic Drugs Topic Facilitated Discussion:** *Questions and Discussion by the PAC*	**Mark Hudak, MD** Chair of the Pediatric Advisory Committee (PAC) **Mark Hudak, MD** Chair of the Pediatric Advisory Committee (PAC)
12:20 p.m.	**LUNCH**	
1:20 p.m.	**Intuniv® (guanfacine ER)** *Questions and Recommendations*	**Amy Taylor, MD, Medical Officer** Division of Pediatric & Maternal Health (DPMH), OND, CDER, FDA
1:50 p.m.	**Banzel™ (rufinamide)** *Questions and Recommendations*	**Jacqueline Spaulding, MD, Medical Officer** DPMH, OND, CDER, FDA
2:15 p.m.	**BREAK**	
2:30 p.m.	**Center for Devices & Radiological Health (CDRH)** **<u>Annual Update of Post-Market HDE Reviews</u>:** **Medtronic Activa® Dystonia Therapy** *Questions and Recommendations*	**Denece Clayborne, RN, MSN** Office of Surveillance and Biometrics (OSB), Product Evaluation Branch III, CDRH, FDA
3:00 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
3:30 p.m.	**Impella® RP System – PMA status update**	**Vasum Peiris, MD, MPH, FAAP, FACC, FASE** Chief Medical Officer – Pediatrics and Special Populations, CDRH, FDA
3:35 p.m.	***Adjournment***	**Mark Hudak, MD** Chair of Pediatric Advisory Committee (PAC)