Pediatric Advisory Committee Meeting
US Food and Drug Administration (FDA) GREAT ROOM (10/11)

FINAL AGENDA **September 20, 2018**		
8:50 a.m.	**Welcome and Introductory Remarks for the Pediatric Advisory Committee Meeting** **<u>Conflict of Interest Statement</u>**	**Robert Dracker, MD, MHA, MBA, CPI,** Chair of Pediatric Advisory Committee (PAC) **Marieann R. Brill, MBA, RAC, MT** Designated Federal Official (DFO), PAC, Office of Pediatric Therapeutics (OPT), Office of Medical Products and Tobacco (OMPT), Office of the Commissioner (OC), FDA
9:02 a.m.	**Opening Remarks**	**Susan McCune, MD,** Director, OPT, OMPT, OC, FDA
9:10 a.m.	**Office of Pediatric Therapeutics Updates**	**Judith U. Cope, MD, MPH** Safety Team Leader, OPT**,** OMPT, OC, FDA
9:16 a.m. – 10:16 a.m.	**Open Public Hearing (1 hour)**	**Marieann R. Brill, MBA** DFO, PAC, OPT**,** OMPT, OC, FDA
	Center for Drug Evaluation and Research (CDER)	
9:22 a.m.	**<u>Standard Review of Adverse Event Presentations</u>** **Lexapro™ (escitalopram oxalate)**	**CDR Courtney M. Suggs, Pharm.D, MPH,** Division of Pharmacovigilance I (DPVI), Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA
	Generic Drugs Topic: **Drug-Ineffective Postmarketing Reports in Drug Safety Surveillance**	**Cindy Kortepeter, Pharm.D,** Director, DPVI**,** OPE, OSE, CDER, FDA
	Generic Drug Development and Safety Evaluation	**Howard D. Chazin, MD, MBA,** Director, Clinical Safety Surveillance Staff, Office of Generic Drugs, CDER, FDA
10:19 a.m.	**Lexapro™ (escitalopram oxalate)** *Questions and Recommendations*	
11:40 a.m.	**BREAK**	
11:55 a.m.	**Intuniv® (guanfacine ER)** *Questions and Recommendations*	**Amy Taylor, MD, MHS,** Medical Officer, Division of Pediatric & Maternal Health (DPMH), OND, CDER, FDA
12:40 p.m.	**LUNCH**	

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1:30 p.m.	**Summary of FDA Completed Review of Pediatric Safety Issues and Updated Labeling Changes for Exjade® (deferasirox)** *Discussion*	**Peter Waldron, MD,** Division of Pharmacovigilance II, OPE, OSE, CDER, FDA **Olanrewaju Okusanya, Pharm.D, MS,** Division of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA **Mona Khurana, MD,** Division of Pediatrics and Maternal Health, Office of Drug Evaluation IV, OND, CDER, FDA **Steve Bird, MS, PhD,** Division of Epidemiology I (DEPII), OPE, OSE CDER, FDA **Kate Gelperin, MD, MPH,** DEPII, OPE, OSE CDER, FDA
2:30 p.m.	**BREAK**	
3:00 p.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, OND, CDER, FDA
3:10 p.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
3:20 p.m.	**Adjourn**	**Robert Dracker, MD,** Chair