

**Pediatric Advisory Committee Meeting
US Food and Drug Administration (FDA) GREAT ROOM ^(4/2)**

DRAFT AGENDA April 8, 2019		
9:00 a.m.	<p>Welcome and Introductory Remarks for the Pediatric Advisory Committee Meeting</p> <p><u>Conflict of Interest Statement</u></p> <p>Opening Remarks</p>	<p>Robert Dracker, MD, MHA, MBA, CPI, Chair of Pediatric Advisory Committee (PAC)</p> <p>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</p> <p>Susan McCune, MD, Director, OPT, OMPT, OC, FDA</p>
Session 1: Introduction		
9:30 a.m.– 9:55 a.m.	Testosterone Replacement Therapy: Current Regulatory Landscape	<p>Christine P. Nguyen, MD, Deputy Director for Safety Division of Bone, Reproductive, and Urologic Products, Office of Drug Evaluation III Office of New Drugs (OND), CDER</p> <p>Ovidiu Galescu, MD, MS, Medical Officer Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, OND, CDER</p>
9:55 a.m. – 10:25 a.m.	Pediatric Male Hypogonadism (current unmet need)	
10:25 a.m. -10:40 a.m.	Testosterone Utilization Patterns Among Pediatric Patients	Corinne Woods, RPh, MPH, Drug Utilization Analyst, Division of Epidemiology II, Office of Surveillance and Epidemiology, OND, CDER
10:45 – 11:00 a.m.	BREAK	

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Session 2: Expert Presentations		
11:00 – 11:30 a.m.	Landscape of Use	Yee-Ming Chan, MD, PhD Assistant Professor of Pediatrics, Harvard Medical School Director, Pediatric Reproductive Hormone Program, Boston Children’s Hospital, Boston, MA
11:30 – 12:00 p.m.	Information needed to support safety and efficacy in pediatric patients Safety concerns associated with misuse/abuse	Stephanie Seminara, MD Professor of Medicine, Harvard Medical School Chief, Reproductive Endocrine Unit, Massachusetts General Hospital, Boston, MA
12:00 – 1:00 p.m.	LUNCH	
1:00 – 2:00 p.m.	Open public hearing	
2:00 – 2:45 p.m.	Industry presentation	Alan D. Rogol, MD, PhD Professor, <i>Emeritus</i> (Pediatrics and Pharmacology) University of Virginia Clinical Professor of Pediatrics, University of Virginia
2:45 – 3:00 p.m.	BREAK	
Session 3: Panel Discussion		
3:00 – 4:30 p.m.	Panel discussion (expert and industry speakers to participate in clarifying questions/discussions)	
4:40 p.m.	Closing Remarks	Robert Dracker, MD, Chair