

FOOD AND DRUG ADMINISTRATION (FDA)

Joint Meeting of the Pediatric Advisory Committee (PAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)

Tommy Douglas Conference Center
10000 New Hampshire Avenue
Silver Spring, Maryland 20903
May 11, 2018

FINAL AGENDA – OPEN SESSION

12:05 p.m	Welcome and Introductions	Mark Hudak, MD Chair, Pediatric Advisory Committee (PAC)
12:10 p.m	Opening Statement	Marieann R. Brill, MBA, RAC, MT(ASCP) Designated Federal Officer, PAC Office of Pediatric Therapeutics (OPT) Office of the Commissioner (OC), FDA
12:15 p.m	Recognition of Service	Susan McCune, MD Director, OPT OC, FDA
12:20 p.m	FDA Presentation	Smita Abraham, MD Medical Officer, Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) CDER, FDA
12:34 p.m	FDA Ethics Presentation	Donna Snyder, MD Pediatric Ethicist/Team Lead OPT OC, FDA
12:47 p.m	Clarifying Questions to FDA	
1:00 p.m.	Open Public Hearing	
2:42 p.m.	Questions to the Committee/Committee Discussion	
3:40 p.m.	Break	
4:03 p.m.	Questions to the Committee/Committee Discussion	
5:15 p.m.	Adjourn for day	Mark Hudak, MD Chair, Pediatric Advisory Committee (PAC)