

Pediatric Advisory Committee Meeting, September 11, 2012

[DoubleTree Hotel](#)

8727 Colesville, Road, Silver Spring, MD, 301-589-5200

AGENDA

Tuesday, September 11, 2012

8:30 am	Welcome and Introductory Remarks	Dianne Murphy, MD, Director Office of Pediatric Therapeutics Office of the Commissioner, FDA Kenneth Towbin, MD, Chair, Chief, Clinical Child and Adolescent Psychiatry Mood and Anxiety Disorders Program NIH, HHS Walter Ellenberg, PhD, Designated Federal Official (DFO), Pediatric Advisory Committee (PAC), Office of Pediatric Therapeutics Office of the Commissioner, FDA
8:45 am	Vyvanse (lisdexamfetamine) Standard Review of Adverse Events <i>Questions and Recommendation</i>	Nadia Hejazi, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
9:45 am	Kapvay (clonidine hydrochloride), Standard Review of Adverse Events <i>Questions and Recommendation</i>	Nadia Hejazi, MD, Medical Officer
10:30 am	BREAK	
10:45 am	Beyaz (drospirenone/ethinyl estradiol/ levemefolate calcium and levomefolate calcium) Standard Review of Adverse Events <i>Questions and Recommendation</i>	Erica Radden, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
11:15 am	PAC Member Directed Abbreviated Review <ul style="list-style-type: none">• Lo Loestrin Fe (norethindrone acetate/ethinyl estradiol)• ella (ulipristal acetate)• Lastacaft (alcaftadine)• Aridol (mannitol inhalation powder) Bronchial Challenge Test Kit• Augmentin XR (amoxicillin/clavulanate potassium)	Kenneth Towbin, MD, Chair
11:30 am	OPEN PUBLIC MEETING	Walter Ellenberg, PhD, DFO, PAC

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12:15 pm	LUNCH	
12:45 pm	Afinitor (everolimus) Standard Review of Adverse Events <i>Questions and Recommendation</i>	Amy Taylor, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
1:30 pm	Ofirmev (acetaminophen injection) Standard Review of Adverse Events Medications Error Review <i>Questions and Recommendation</i>	Donna Snyder, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA Denise Baugh, PharmD, Division of Medication Error Prevention and Analysis, CDER, FDA
2:15 pm	Sponsor presentation	Mike Royal, MD, JD, Vice President of Medical Affairs and Clinical Development, Cadence Pharmaceuticals
2:30 pm	Melody Transcatheter <i>Questions and Recommendation</i>	John S. Sapirstein, MD Office of Device Evaluation, CDRH Jenny Liu, RN, BSN, MSN Nurse Consultant, Office of Surveillance and Biometrics, CDRH Dale R. Tavriss, MD, MPH, Epidemiologist, Office of Surveillance and Biometrics, CDRH
3:30 pm	Elana Surgical Kit HUD <i>Questions and Recommendation</i>	Mo Bydon, MD, Office of Device Evaluation, CDRH Cara J. Krulewitch, CNM, Ph.D., FACNM Office of Surveillance and Biometrics, CDRH
4:15 pm	Closing Remarks/Adjourn	Kenneth Towbin, MD, Chair