

Pediatric Advisory Committee Meeting

Wednesday, September 14th

[Double Tree by Hilton Hotel](#)

8120 Wisconsin Ave, Bethesda, MD 20814

(301) 652-2000

DRAFT AGENDA

8:00	Welcome Introductory Remarks, and recognitions	Mark Hudak, MD Chair of Pediatric Advisory Committee (PAC) Marieann Brill, MBA, RAC, MT(ASCP) Designated Federal Official, PAC Office of Pediatric Therapeutics (OPT) Office of the Commissioner (OC), FDA
8:30	Open Public Hearing	Marianne Brill, MBA, RAC, MT(ASCP) Designated Federal Official, PAC
9:30	Center for Drug Evaluation and Research (CDER) <u>Sustiva (efavirenz)</u> <i>Questions and Recommendations</i>	Carolyn Yancey, MD Division of Pediatric and Maternal Health, (DPMH), CDER, FDA
10:00	Center for Biologics Evaluation and Research (CBER) <u>Abbreviated Presentations</u> <u>MENVEO [Meningococcal (groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]</u> <i>Questions and Recommendations</i> <u>IXIARO (Japanese encephalitis vaccine)</u> <i>Questions and Recommendations</i>	Judith Cope, MD, MPH, Medical Officer, OPT, OC, FDA
10:15	BREAK	
10:30	<u>Topamax (topiramate)</u> <i>Questions and Recommendations</i>	Mona Khurana, MD, Medical Officer, DPMH, CDER, FDA
11:00	<u>Asacol & Asacol HD, and Delzicol (mesalamine)</u> <i>Questions and Recommendations</i>	LCDR Erica Radden, MD, Medical Officer
11:30	<u>Kepivance (palifermin)</u> <i>Questions and Recommendations</i>	LCDR Erica Radden, MD, Medical Officer, DPMH, CDER, FDA

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12:00	Update on Exjade (deferasirox)	Peter Waldron, MD, Medical Officer, Division of Pharmacovigilance II, OSE, CDER, FDA
12:15	LUNCH	
1:00	<u>Bloxiverz (neostigmine methylsulfate)</u> <i>Questions and Recommendations</i>	Amy Taylor, MD, MHS, Medical Officer DPMH, CDER, FDA
1:15	<u>Doryx (doxycycline hyclate)</u> <i>Questions and Recommendations</i>	Amy Taylor, MD, MHS, Medical Officer DPMH, CDER, FDA
1:45	<u>Xolair (omalizumab)</u> <i>Questions and Recommendations</i>	Amy Taylor, MD, MHS, Medical Officer DPMH, CDER, FDA
2:00	<u>Karbinal ER (carbinoxamine maleate)</u> <i>Questions and Recommendations</i>	Ethan Hausman, MD, Medical Officer, DPMH, CDER, FDA
2:30	Pregnancy and Lactation Labeling Rule (PLLR) presentation	LCDR Miriam Dinatale, D.O., Medical Officer, DPMH, CDER, FDA
3:00	Tutorial - Review postings on the web	LCDR Kenneth Quinto, MD, MPH, Medical Officer, OPT, OC, FDA
3:15	BREAK	
3:30	Center for Devices and Radiological Health (CDRH) <u>Annual Post-Market HDE Reviews:</u> <u>Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD)</u> <i>Questions and Recommendations</i>	Rebecca Ward, MPH Epidemiologic Evaluation and Research Branch I, Division of Epidemiology, Office of Surveillance and Biometrics, CDRH, FDA

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3:45	<u>CONTEGRA Pulmonary Valved Conduit</u> <i>Questions and Recommendations</i>	George Aggrey, MD, MPH, Epidemiologic Evaluation and Research Branch I, Division of Epidemiology, Office of Surveillance and Biometrics, CDRH, FDA
4:00	<u>Pleximmune</u> <i>Questions and Recommendations</i>	Kellie Kelm, PhD, Cardio-Renal Diagnostics Branch Division of Chemistry and Toxicology Devices, Office of In Vitro Diagnostics Devices and Radiological Health, CDRH, FDA
4:15	<u>Enterra™ Therapy System</u> <i>Questions and Recommendations</i>	Catherine Ricketts, RN, BSN Product Evaluation Branch II Division of Postmarket Surveillance Office of Surveillance and Biometrics, CDRH, FDA
4:30	<u>Elana Surgical Kit (HUD)</u> <i>Questions and Recommendations</i>	Colin Anderson-Smits, MPH Epidemiologic Evaluation and Research Branch II, Division of Epidemiology, Office of Surveillance and Biometrics, CDRH, FDA
4:45	Wrap-up and Adjournment	Mark Hudak, MD, Chair