

Pediatric Advisory Committee Meeting

Wednesday, September 14th

[Double Tree by Hilton Hotel](#)

8120 Wisconsin Ave, Bethesda, MD 20814

(301) 652-2000

FINAL 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
8:15	Tutorial - Review postings on the web	LCDR Kenneth Quinto, MD, MPH, Medical Officer, OPT, OC, FDA
8:30	Open Public Hearing	Marianne Brill, MBA, RAC, MT (ASCP) Designated Federal Official, PAC
8:35	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
8:45	BREAK	
9:00	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
10:10	<u>Topamax (topiramate)</u> <i>Questions and Recommendations</i>	Mona Khurana, MD, Medical Officer, DPMH, CDER, FDA
10:35	BREAK	

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10:50	<u>Asacol & Asacol HD, and Delzicol (mesalamine)</u> <i>Questions and Recommendations</i>	LCDR Erica Radden, MD, Medical Officer, DPMH, CDER, FDA
11:20	<u>Kepivance (palifermin)</u> <i>Questions and Recommendations</i>	LCDR Erica Radden, MD, Medical Officer, DPMH, CDER, FDA
11:30	Update on Exjade (deferasirox)	Peter Waldron, MD, Medical Officer, Division of Pharmacovigilance II, OSE, CDER, FDA
11:40	Pregnancy and Lactation labeling Rule (PLLR) presentation	LCDR Miriam Dinatale, D.O., Medical Officer, DPMH, CDER, FDA
12:00	LUNCH	
1:00	<u>Bloxiverz (neostigmine methylsulfate)</u> <i>Questions and Recommendations</i>	Amy Taylor, MD, MHS, Medical Officer DPMH, CDER, FDA
1:20	<u>Doryx (doxycycline hyclate)</u> <i>Questions and Recommendations</i>	Amy Taylor, MD, MHS, Medical Officer DPMH, CDER, FDA
1:35	<u>Xolair (omalizumab)</u> <i>Questions and Recommendations</i>	Amy Taylor, MD, MHS, Medical Officer DPMH, CDER, FDA
1:50	<u>Karbinal ER (carbinoxamine maleate)</u> <i>Questions and Recommendations</i>	Ethan Hausman, MD, Medical Officer, DPMH, CDER, FDA
2:05	BREAK	
2:20	Center for Devices and Radiological Health (CDRH) <u>Annual Post-Market HDE Reviews:</u> Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD) <i>Questions and Recommendations</i>	Rebecca Ward, MPH Product Evaluation Branch I, Division of Postmarket Surveillance (DPS), Office of Surveillance and Biometrics (OSB), CDRH, FDA

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3:05	<u>CONTEGRA Pulmonary Valved Conduit</u> <i>Questions and Recommendations</i>	George Aggrey, MD, MPH, Epidemiology Evaluation and Research Branch I, Division of Epidemiology, OSB, CDRH, FDA
3:30	<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 and Radiological Health, CDRH, FDA
4:00	<u>Enterra™ Therapy System</u> <i>Questions and Recommendations</i>	Catherine Ricketts, RN, BSN Product Evaluation Branch II, DPS, OSB, CDRH, FDA
4:15	<u>Elana Surgical Kit (HUD)</u> <i>Questions and Recommendations</i>	Colin Anderson-Smits, MPH Epidemiology Evaluation and Research Branch II, Division of Epidemiology, OSB, CDRH, FDA
4:25	Wrap-up and Adjournment	Mark Hudak, MD, Chair