

**Pediatric Advisory Committee Meeting**

**Thursday, March 14, 2013**

Sheraton Silver Spring  
8777 Georgia Avenue,  
Silver Spring, Maryland, 20910

**DRAFT AGENDA**

- 8:00 a.m. Welcome and Introductory Remarks
- Kenneth Towbin, MD  
Chair of Pediatric Advisory Committee (PAC)  
Chief, Clinical and Adolescent Psychiatry, Mood and Disorders Program, National Institute of Mental Health
- Walter Ellenberg, PhD  
Designated Federal Official, PAC  
Office of Pediatric Therapeutics  
Office of the Commissioner (OC), FDA
- 8:10 a.m. Agenda Overview
- Dianne Murphy, MD, Director  
Office of Pediatric Therapeutics  
OC, FDA
- 8:15 a.m. **Menactra Meningococcal (Groups A,C,Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine)**
- Bethany Baer, MD Medical Officer,  
Division of Epidemiology,  
Office of Biostatistics and Epidemiology,  
CBER
- Post-Licensure and Adverse Event Review  
*Questions and Recommendations*
- 9:00 a.m. Modification of CBER Presentations to the Pediatric Advisory Committee (PAC)
- Barbara Buch, MD  
Associate Director for Medicine,  
CBER
- 9:05 a.m. CBER Justified Abbreviated Presentation  
**Hizentra Globulin Subcutaneous (Human) 20% Liquid**  
*Questions and Recommendations*
- Judith Cope, MD, MPH, Medical Officer,  
Office of Pediatric Therapeutics, OC,  
FDA
- 9:20 a.m. CDER Justified Abbreviated: rationale provided  
**Alimta (pemetrexed disodium)**  
*Questions and Recommendations*
- Judith Cope, MD, MPH

**Pediatric Advisory Committee Meeting**

**Thursday, March 14, 2013**

Sheraton Silver Spring  
8777 Georgia Avenue,  
Silver Spring, Maryland, 20910

**DRAFT AGENDA**

	<b>Gadavist (gadobutrol)</b> <i>Questions and Recommendations</i>	Judith Cope, MD, MPH, Medical Officer
9:35 a.m.	<u>Abbreviated: CBER and CDER</u>	Judith Cope, MD, MPH, Medical Officer
	<b>Kedbumin Albumin (Human)</b> <i>Questions and Recommendations</i>	
	<b>Natroba (spinosad)</b> <i>Questions and Recommendations</i>	
9:45 a.m.	<u>Designated Abbreviated Review Process</u>	Judith Cope, MD, MPH, Medical Officer
	<b>Uroxatral (alfuzosin hydrochloride)</b> <b>Creon (pancrelipase)</b> <b>Zenpep (pancrelipase)</b>	
9:50 a.m.	<b>Break</b>	
10:00 a.m.	<u>Standard Review of Adverse Event Presentations</u>	
	<b>Moxeza (moxifloxacin Ophthalmic Solution 0.5%)</b>	Amy Taylor, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
	<b>Approach to Pediatric Bacterial Conjunctivitis</b> <i>Questions and Recommendations</i>	Wiley Chambers, MD, Supervisory Medical Officer, Division of Transplant and Ophthalmology Products, CDER, FDA
10:20 a.m.	<b>Kytril Injection (granisetron hydrochloride) and a Class Review of 5-HT<sub>3</sub> Receptor Antagonists</b> <i>Questions and Recommendations</i>	Donna Snyder, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
11:00 a.m.	<b>Nexium (esomeprazole magnesium) &amp; Nexium IV (esomeprazole sodium)</b> <i>Questions and Recommendations</i>	Amy Taylor, MD, Medical Officer
11:30 p.m.	<b>Open Public Hearing</b>	Walter Ellenberg, PhD

**Pediatric Advisory Committee Meeting**

**Thursday, March 14, 2013**

Sheraton Silver Spring  
8777 Georgia Avenue,  
Silver Spring, Maryland, 20910

**DRAFT AGENDA**

12:30 p.m. **Lunch**

1:30 p.m. **INOmax (nitric oxide)**  
*Questions and Recommendations*

Erica Radden, MD, Medical Officer  
Pediatric & Maternal Health Staff,  
Office of New Drugs, CDER, FDA

2:15 p.m. **Background Information on Systemic  
Juvenile Idiopathic Arthritis (SJIA)**  
*Questions and Clarifications*

Laura E. Schanberg, MD  
Professor of Pediatrics  
Co-Chief, Division of Pediatrics  
Rheumatology  
Duke University School of Medicine

2:30 p.m. **Actemra (tocilizumab)**  
*Questions and Recommendations*

Donna Snyder, MD, Medical Officer

3:10 p.m. **Lamictal XR (lamotrigine)**  
*Questions and Recommendations*

Donna Snyder, MD, Medical Officer

3:40 p.m. **Break**

3:50 p.m. **Invega (paliperidone)**  
*Questions and Recommendations*

Alyson Karesh, MD, Medical Officer  
Pediatric & Maternal Health Staff,  
Office of New Drugs, CDER, FDA

4:45 p.m. **INFORMATIONAL UPDATE**  
**Pharmacogenetics of Codeine**

Yeruk "Lily" Mulugeta, Pharm.D  
Clinical Pharmacology Reviewer  
Office of Clinical Pharmacology,  
Office of Translational Sciences,  
CDER, FDA

5:00 p.m. **Death and respiratory arrest related to ultra-  
rapid metabolism of codeine to morphine**

Judith Racoosin, MD, MPH  
Deputy Director of Safety,  
Division of Anesthesia, Analgesia, and  
Addition Products, CDER, FDA

5:30 p.m. **Adjournment**

Kenneth Towbin, MD