

**Pediatric Advisory Committee Meeting  
November 29, 2006**

Hilton Washington DC North/Gaithersburg, Grand Ballroom,  
620 Perry Parkway, Gaithersburg, Maryland

8:00AM	Welcome and Introductory Remarks	Marsha Rappley, MD Chair Dean, College of Human Medicine Michigan State University
		Carlos Peña, PhD, MS Executive Secretary Office of Science and Health Coordination OC, FDA
8:10	Introduction	CDR Lisa Mathis, MD Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs Center for Drug Evaluation and Research Food and Drug Administration
8:20	Background on Draft Guidance for Clinical Lactation Studies	Karen B. Feibus, MD Medical Team Leader, Maternal Health Team Office of New Drugs Center for Drug Evaluation and Research Food and Drug Administration
8:50		Charles Bonapace, PharmD Office of Clinical Pharmacology Center for Drug Evaluation and Research Food and Drug Administration
9:00	Breastfeeding Physiology, Benefits and Research	Ruth Lawrence, MD, Neonatologist Professor of Pediatrics, Obstetrics, & Gynecology University of Rochester Medical Center Director, Newborn Nursery, Golisano Children's Hospital
	<i>Qs &amp; As</i>	
9:40	Physiology and Pharmacology of Drugs in Breast Milk	Thomas W. Hale, PhD, RPh Clinical Pharmacologist and Professor Texas Tech University School of Medicine
	<i>Qs &amp; As</i>	
10:20	Break	
10:40	Ethical Issues in Conducting Clinical Lactation Studies	Robert Nelson, MD, PhD Pediatric Ethicist Office of Pediatric Therapeutics, OC, FDA
11:20	<i>Discussion of Background &amp; Presentations</i>	
11:50	Lunch	

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1:00PM *Open Public Hearing*

2:00 *Committee Deliberations and Qs & As*

4:00 Adjourn

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