

Pediatric Advisory Committee Meeting
November 18, 2008
Holiday Inn/Gaithersburg, Grand Ballroom,
2 Montgomery Village Road, Gaithersburg, Maryland

8:00	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	Agenda Overview	Dianne Murphy, MD, Director, Office of Pediatric Therapeutics OC, FDA
8:20	Zyvox (linezolid) Report Requested at the November 16, 2006 Pediatric Advisory Committee meeting (report in the briefing packet)	Opportunity for Questions from the Committee
	Betoptic S (betaxolol) and Timolol (timolol) Abbreviated Process	Opportunity for Questions from the Committee
8:30	Risperdal (risperidone) Standard Review of Adverse Events	Felicia Collins, MD, MPH, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
8:50	<i>Questions and Recommendation</i>	
9:00	Zyprexa (olanzapine) Standard Review of Adverse Even	Felicia Collins, MD, MPH Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
9:20	<i>Questions and Recommendation</i>	
9:30	Levaquin (levofloxacin) Standard Review of Adverse Events	Elizabeth L. Durmowicz, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
9:50	<i>Questions and Recommendation</i>	
10:00	Break	

Pediatric Advisory Committee Meeting
November 18, 2008
Holiday Inn/Gaithersburg, Grand Ballroom,
2 Montgomery Village Road, Gaithersburg, Maryland

10:15	Lamictal (lamotrigine) Standard Review of Adverse Events	Felicia Collins, MD, MPH, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
10:35	<i>Questions and Recommendation</i>	
10:45	Ambien (zolpidem) Standard Review of Adverse Events	Elizabeth L. Durmowicz, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
11:05	<i>Questions and Recommendation</i>	
11:15	Lamisil (terbinafine) Standard Review of Adverse Events	Patricia Brown, MD, Medical Officer Division of Dermatology and Dental Products, Office of New Drugs, CDER, FDA
11:35	<i>Questions and Recommendation</i>	
11:45	Aldara (imiquimod) Standard Review of Adverse Events	Amy Taylor, MD, MHS, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
12:05	<i>Questions and Recommendation</i>	
12:15	Lunch	
1:30	Open Public Hearing	
2:30	Sandostatin (octreotide) Expanded Review of Adverse Events <i>Outside Speaker Presentation</i>	Rama Bhat, MD Professor of Pediatrics Director of Neonatology University of Illinois at Chicago Medical Center
2:50	<i>Clarification Questions</i>	
3:00	FDA Presentation	Amy Taylor, MD, MHS, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
3:20	Sponsor Presentation	Todd Gruber, MD, MPH Head, U.S. Medical Function Novartis
3:30	<i>Questions and Recommendation</i>	

Pediatric Advisory Committee Meeting
November 18, 2008
Holiday Inn/Gaithersburg, Grand Ballroom,
2 Montgomery Village Road, Gaithersburg, Maryland

3:45

Ethics Discussion

Robert "Skip" Nelson, MD, PhD
Pediatric Ethicist, Office of Pediatric
Therapeutics, OC, FDA

4:45

Adjourn

Dianne Murphy, MD, Director,
Office of Pediatric Therapeutics, OC, FDA

DRAFT