

Pediatric Advisory Committee

Agenda

November 18, 2005

Washington-North Hilton, Gaithersburg, Maryland

8:00 a.m.	Call to Order Introductions, Meeting Statement	Robert Nelson, M.D., Ph.D. (Chair)
8:15 a.m.	Overview of Agenda Committee Role in BPCA Safety Reviews	Dianne Murphy, M.D. Solomon Iyasu, M.D., M.P.H.
8:30 a.m.	Open Public Hearing	
9:30 a.m.	Sumatriptan (IMITREX®) Irinotecan (CAMPTOSAR®) Carboplatin (PARAPLATIN®) Rofecoxib (VIOXX®) Anagrelide (AGRYLIN®) Sodium Ferric Gluconate (FERRLECTIT®) Fluconazole (DIFLUCAN®)	Suzie McCune, M.D. Division of Pediatric Drug Development OCTAP, CDER, FDA Larry Grylack, M.D. Division of Pediatric Drug Development OCTAP, CDER, FDA
10:30 a.m.	BREAK	
10:45 a.m.	One-Year Post-Exclusivity Adverse Event Reports for Oseltamivir (TAMIFLU®)	Melissa Truffa, R.Ph. Division of Drug Risk Evaluation Office of Drug Safety. CDER, FDA
11:15 a.m.	Review of Literature and Clinical Trial Data for Oseltamivir (TAMIFLU®)	Linda Lewis, M.D. Division of Anti-Viral Products Office of New Drugs, CDER. FDA
11:45 p.m.	Sponsor Presentation	Roche Representative
12:05 a.m.	Surveillance Data on Influenza: Pediatric Deaths and Central Nervous System Adverse Events	David Shay, M.D., M.P.H. CDC
12:35 p.m.	Q & As	
12:50 p.m.	Summary of Agency Action Plan and Charge to Committee	Linda Lewis, M.D
1:00 p.m.	Discussion	
1:30 p.m.	Adjourn	