FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)

Hyatt Regency Dallas at Reunion

300 Reunion Boulevard, Dallas, Texas 75207

March 2, 2011

AGENDA

7:15 a.m.	Call to Order	Jürgen Venitz, M.D., Ph.D. Acting Chair, ACPS-CP
	Conflict of Interest Statement	Yvette Waples, Pharm.D. Designated Federal Officer
7:30 a.m.	Introduction and Background	Lawrence Lesko, Ph.D. Director, Office of Clinical Pharmacology (OCP), Office of Translational Science (OTS), CDER, FDA
8:00 a.m.	FDA perspective on rare disease drug development and regulation	Tim Cote, M.D., MPH Director, Office of Orphan Products Development, FDA
8:30 a.m.	A Paradox in Orphan Drug Development	Trevor Mundel, M.D., Ph.D.(Guest Speaker) Global Head of Development Novartis Pharma AG
9:00 a.m.	A clinical pharmacology decision tree for orphan drugs	Dennis Bashaw, Pharm.D. Director, Division of Clinical Pharmacology III, OCP, OTS, CDER, FDA
9:30 a.m.	Clinical pharmacology tools for developing drugs for rare diseases	Christine Garnett, Pharm.D. Associate Director of Operations, Pharmacometrics, OCP, OTS, CDER, FDA
10:00 a.m.	**BREAK**	
10:15 a.m.	Future perspectives on academic-industry-government collaboration on orphan drug development	James Cloyd, Pharm.D. Professor, Director of Center for Orphan Drug Development, University of Minnesota
10:45 a.m.	Open Public Hearing	
11:45 a.m.	**LUNCH**	
12:45 p.m.	Committee Questions and Discussions	
2:20 p.m.	FDA next steps	Anne Pariser, M.D. Associate Director for Rare Diseases Office of New Drugs (OND), CDER, FDA
2:35 p.m.	FDA Closing Remarks/Adjourn	Lawrence Lesko, Ph.D.