Pediatric Advisory Committee

Food and Drug Administration
ACS Conference Room, Room 1066
5630 Fishers Lane, Rockville, Maryland 20857

Agenda for September 15, 2004
8:00-2:00 pm

8:00	**Call to Order, Introductions**	Chair, Pediatric Advisory Committee
	Meeting Statement	Jan Johannessen, PhD Executive Secretary
8:20	**Subpart D Referral Process**	Sara F. Goldkind, MD, MA Bioethicist, Office of Pediatric Therapeutics
8:25	**Summary of Deliberations of Pediatric Ethics Subcommittee held on 9-10-04**	Chair, Pediatric Ethics Subcommittee
9:10	**Overview of Adverse Event Reporting as Mandated by BPCA**	Solomon Iyasu, MD Medical Epidemiologist, Office of Pediatric Therapeutics
9:25	**Adverse Event Reporting**	
	Ocuflox (ofloxacin) Fosamax (alendronate)	Hari Sachs, MD Medical Officer Division of Pediatric Drug Development
	Fludara (fludarabine)	Susan McCune, MD Medical Officer Division of Pediatric Drug Development
	Clarinex (desloratadine)	Jane Filie, MD Medical Officer Division of Pediatric Drug Development
10:25	**Break**	

10:40 **Adverse Event Reporting for Drug Products Containing Budesonide or Fluticasone: Pulmicort, Rhinocort, Flonase, Flovent, Advair, and Cutivate**

Peter Starke, MD
Medical Team Leader
Division of Pulmonary Drug Products

Joyce Weaver, Pharm. D.
Safety Evaluator
Division of Drug Risk Evaluation

11:30 **Open Public Hearing**

12:30 **Final Comments and Adjourn**