Pediatric Advisory Committee

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

FINAL Agenda for September 15, 2004

8:00	**Call to Order, Introductions**	P. Joan Chesney, M.D. Chair, Pediatric Advisory Committee
	Meeting Statement	Jan N. Johannessen, Ph.D. Executive Secretary
8:20	**Subpart D Referral Process**	Sara F. Goldkind, M.D., M.A. Bioethicist, Office of Pediatric Therapeutics
8:25	**Summary of Deliberations of Pediatric Ethics Subcommittee held on 9-10-04**	P. Joan Chesney, M.D. Chair, Pediatric Advisory Committee Robert Nelson, M.D., Ph.D. Chair, Pediatric Ethics Subcommittee Bernard Schwetz, D.V.M., Ph.D. Director, Office for Human Research Protections, HHS
9:10	**Overview of Adverse Event Reporting as Mandated by BPCA**	Solomon Iyasu, M.D. Medical Epidemiologist, Office of Pediatric Therapeutics
9:25	**Adverse Event Reporting**	
	Ocuflox (ofloxacin) Fosamax (alendronate)	Hari Sachs, M.D. Medical Officer Division of Pediatric Drug Development
	Fludara (fludarabine)	Susan McCune, M.D. Medical Officer Division of Pediatric Drug Development
	Clarinex (desloratadine)	Jane Filie, M.D. 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, M.D.
Medical Team Leader
Division of Pulmonary Drug Products

ShaAvhree Buckman, M.D., Ph.D., FAAP
Medical Officer
Division of Pediatric Drug Development

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

Badrul A. Chowdhury, MD, PhD
Director, Div of Pulmonary and Allergy Drug Products
CDER, FDA

11:30 **Open Public Hearing**

12:30 **Final Comments and Adjourn**

P. Joan Chesney, M.D.
Chair, Pediatric Advisory Committee