Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
ACS Building, 5630 Fishers Lane, Rockville, MD

Timing of the initiation of pediatric oncology clinical studies in a drug development program

Agenda for October 17, 2002

8:00	**Call to order and Introduction**	Victor M. Santana, M.D., Chair
	Welcome	Richard Pazdur, M.D., Director, Division of Oncology Drug Products
	Conflict of Interest	Thomas H. Perez, M.P.H., Executive Secretary
8:15	**Charge to Committee**	Steven Hirschfeld, M.D, PhD., Medical Officer Division of Oncology Drug Products
8:20	**Preclinical Models: What can they tell us**	Peter Houghton, Ph.D.
8:35	**Applying Preclinical Data to Clinical Studies**	Edward Sausville, M.D.
8:45	**Applying Preclinical Data to Clinical Studies**	Patrick C. Reynolds, M.D.
8:55	**Committee Discussion**	
	Current Practice	
9:10	**Children's Oncology Group Perspective**	Peter Adamson, M.D.
9:20	**Industry Perspective**	Steve Weitman, M.D.
9:30	**European Perspective**	Bruce Morland, M.D.
9:35	**European Perspective**	Joachim Boos, M.D.
9:40	**Committee Discussion**	
9:55	***Break***	
	Identifying & Overcoming Barriers:	
10:10	**Children's Oncology Group Perspective**	Gregory Reaman, M.D.
10:20	**National Cancer Institute Perspective**	Barry Anderson, M.D. Ph.D.
10:30	**Children's Hospital & Specialty Group Perspective**	Susan Blaney, M.D.
10:40	**Industry Perspective**	David Emanuel, M.D.
10:50	**Industry Perspective**	Wayne Rackoff, M.D.
10:55	**Patient & Family Perspective**	Ruth Hoffman
11:05	**Committee Discussion**	
12:00	**Lunch**	
1:00	**Open Public Hearing**	
2:00	**Questions to the Panel**	
4:00	**Adjourn**	