FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

March 14th, 2006

Pediatric Oncology Subcommittee of the Oncology Drugs Advisory Committee Meeting

Gaithersburg Hilton, Gaithersburg, MD

AGENDA

8:00 a.m.	Call to Order Introduction of Committee	**Gregory H. Reaman, M.D.** Chair, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee
	Conflict of Interest Statement	**Johanna Clifford, M.Sc., RN** Executive Secretary, Pediatric Oncology Subcommittee of the ODAC/CDER/FDA

The subcommittee will discuss (1) clinical studies of methotrexate and daunomycin to be conducted under the Best Pharmaceuticals for Children Act (BPCA) ; and (2) phase 4 requirements for Deferasirox (Exjade®), Novartis Pharmaceuticals, as mandated under Accelerated Approval;

8:10 a.m.	Opening Remarks	**Karen Weiss, M.D., Deputy Director,** Office of Oncology Drug Products (OODP)/CDER/FDA
8:15 a.m.	Daunomycin Proposal	**Stacy Berg, M.D.** Texas Children's Cancer Center Baylor College of Medicine
8:35 a.m.	High Dose MTX Toxicity & Safety	**Malcolm Smith, M.D., Ph.D.** Associate Branch Chief, Pediatrics Cancer Therapy Evaluation Program (CTEP), National Cancer Institute (NCI), NIH & **Daniel Armstrong, M.D.** University of Miami School of Medicine
9:15 a.m.	*Open Public Hearing*	
9:30 a.m.	*Questions to the Subcommittee & Subcommittee Discussion*	
10:15 a.m.	*Break*	
10:30 a.m.	Review of Exjade Approval	**George Shashaty, M.D., Medical Officer,** Division of Medical Imaging and Hematology Products, OODP/OND/CDER
10:50	**Sponsor Presentation** Post Marketing Commitments with Exjade (NDA 21-882)	**Novartis Pharmaceuticals Corporation** Renaud Capdeville, M.D., Deputy Head Phase II/III Group Clinical Oncology
11:00 a.m.	*Open Public Hearing*	
11:15 a.m.	*Questions to the Subcommittee and Subcommittee Discussion*	
12:15 p.m.	Lunch	

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AGENDA CONT'D

The committee will discuss CDER's process for handling drug shortages .

1:15 p.m.	An Industry Perspective: Drug Shortages in Pediatric Oncology	**Wayne Rackoff, M.D**. Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
1:45 p.m.	CDER Drug Shortages Program	**Mark J. Goldberger, MD, MPH** Drug Shortage Coordinator, CDER, FDA Director, Office of Antimicrobial Products, OND, CDER, FDA
2:15 p.m.	*Open Public Hearing*	
2:45 p.m.	*Break*	
3:00 p.m.	*Questions to the Subcommittee and Subcommittee Discussion*	
4:30 p.m.	*Adjourn*	