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

October 20, 2005

Pediatric Oncology Subcommittee of the Oncology Drugs Advisory Committee Meeting

Advisors and Consultants Conference Room, #1066, Rockville, Maryland

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 (ODAC)/ CDER/FDA
	Conflict of Interest Statement	Victoria Ferretti-Aceto, Pharm.D. Executive Secretary, Pediatric Oncology Subcommittee of the ODAC/CDER/FDA

The subcommittee will hear about the structure and function of the Office of Oncology Drug Products in CDER and discuss issues involved with the conduct of certain pediatric post-marketing studies for products approved for oncologic indications

8:10 a.m.	Opening Remarks	Karen Weiss, M.D. Deputy Director, Office of Oncology Drug Products (ODP)/CDER/FDA
8:15 a.m.	Introduction of CDER's Office of Oncology Products	Richard Pazdur, M.D. Director, ODP/CDER/FDA

<u>Accelerated Approval and Clolar™ (clofarabine) Required Confirmatory Trials</u>

8:30 a.m.	FDA Presentation	Martin Cohen, M.D. Medical Officer, Division of Drug Oncology Products/ODP/CDER/FDA
8:50 a.m.	Genzyme Presentation	Rekha Abichandani, M.D. Medical Director, Clinical Research, Genzyme Corporation
9:10 a.m.	*Questions from the Subcommittee & Discussion*	
9:30 a.m.	*Break*	
9:45 a.m.	Pediatric Drug Development Initiatives	Lisa Mathis, M.D. Acting Director, Division of Pediatric Drug Development, Office of Counterterrorism and Pediatrics/CDER/FDA
10:00 a.m.	*Questions from the Subcommittee*	

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Pediatric Post-Marketing Commitments

Neulasta® (pegfilgrastim)

10:15 a.m.	FDA Presentation	Jeff Summers, M.D. Medical Officer, Division of Biologic Oncology Products/ODP/CDER/FDA
10:30 a.m.	Amgen Presentation	Lyndah Dreiling, M.D. Director, Clinical Development, Amgen, Inc.

Kepivance™ (palifermin)

10:45 a.m.	FDA Presentation	Joseph Gootenberg, M.D. Medical Team Leader, Division of Biologic Oncology Products/ODP/ CDER/FDA
11:00 a.m.	Amgen Presentation	Dietmar Berger, M.D., Ph.D. Director, Clinical Development, Amgen, Inc.
11:15 a.m.	*Questions from the Subcommittee & Discussion*	
11:45 a.m.	Open Public Hearing	
12:15 p.m.	*Lunch*	

The committee will review the status of studies for specific off-patent drugs for pediatric oncology, and consider other off-patent oncology drugs for which pediatric studies are needed, as mandated by the Best Pharmaceuticals for Children Act.

1:15 p.m.	The Best Pharmaceuticals for Children Act (BPCA)	Anne Zajicek, M.D., Pharm.D. Pediatric Medical Officer, National Institute of Child Health and Human Development, NIH
1:45 p.m.	Actinomycin-D/Vincristine in Pediatric Oncology Trials	Jeffery Barrett, Ph.D., FCP Division of Clinical Pharmacology & Therapeutics, The Children's Hospital of Philadelphia
2:15 p.m.	*Questions from the Subcommittee & Discussion*	
2:45 p.m.	*Break*	
3:00 p.m.	Open Public Hearing	
3:30 p.m.	Future Subcommittee Topics	Karen Weiss, M.D. ODP/CDER/FDA
4:00 p.m.	Adjourn	