

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Pediatric Oncology Subcommittee

of the

Oncologic Drugs Advisory Committee

AGENDA

June 27, 2007

The subcommittee will discuss/review oncology products granted pediatric exclusivity under the Best Pharmaceuticals for Children Act (BPCA).

8:00 a.m.	Call to Order Introduction of Committee	Michael Link, M.D. Acting Chair, Pediatric Oncology Subcommittee
	Conflict of Interest Statement	Mimi Phan, Pharm.D., R.Ph. Acting Designated Federal Official, Pediatric Oncology Subcommittee
8:10 a.m.	Opening Remarks	Karen Weiss, M.D. Deputy Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA
8:15 a.m.	Pediatric Oncology and the Best Pharmaceuticals for Children Act	Lisa Mathis, M.D. Associate Director, Pediatric and Maternal Health Staff, OND, CDER, FDA
8:30 a.m.	BPCA Experience with Oncology Drugs	Victor Santana, M.D. FDA/CDER/OODP Guest Worker from St. Jude Children's Research Hospital
9:15 a.m.	<i>Questions to the Presenters</i>	
9:45 a.m.	Break	
10:00 a.m.	Open Public Hearing	
10:30 a.m.	<i>Questions to the Pediatric Oncology Subcommittee and Discussion</i>	
11:15 p.m.	Lunch	

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The subcommittee will discuss 13-cis retinoic acid: summary of clinical experience and additional clinical studies for the treatment of patients with neuroblastoma to be conducted under the BPCA.

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| 12:15 a.m. | Call to Order
Introduction of Committee | Michael Link, M.D.
Acting Chair, Pediatric Oncology Subcommittee |
| | Conflict of Interest Statement | Mimi Phan, Pharm.D., R.Ph.
Acting Designated Federal Official, Pediatric Oncology Subcommittee |
| 12:25 p.m. | The Best Pharmaceuticals for Children Act | Anne Zajicek, M.D., Pharm.D.
Pediatric Medical Officer, National Institute of Child Health & Human Development, NIH |
| 12:45 p.m. | Isotretinoin Phase 1 PK/Phase 3 data | C. Patrick Reynolds, M.D., Ph.D.
Director, Developmental Therapeutics Program, USC-CHLA Institute for Pediatric Clinical Research, Children's Hospital Los Angeles;
Professor of Pediatrics, Keck School of Medicine, The University of Southern California |
| 1:00 p.m. | Cooperative Clinical Trials with 13-cis-Retinoic Acid in Neuroblastoma | Katherine Matthay, M.D.
University of California, San Francisco
Children's Oncology Group |
| 1:15 p.m. | <i>Questions to the Presenters</i> | |
| 1:45 p.m. | Break | |
| 2:00 p.m. | Open Public Hearing | |
| 2:30 p.m. | <i>Questions to the Pediatric Oncology Subcommittee and Discussion</i> | |
| 4:00 p.m. | Adjourn | |