

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Pediatric Oncology Subcommittee*

*of the*

*Oncologic Drugs Advisory Committee*

## AGENDA

April 16, 2008

8:30 a.m.	Call to Order Introduction of Committee	<b>Michael Link, M.D.</b> Acting Chair, Pediatric Oncology Subcommittee
	Conflict of Interest Statement	<b>Nicole Vesely, PharmD</b> Designated Federal Official Pediatric Oncology Subcommittee

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*The Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee will consider and discuss opportunities for enhancing global pediatric oncology drug development and expanding international regulatory interactions given the January 2007 legislation introduced in the European Union that governs the development and authorization of medicines for use in children aged 0 to 17 years.*

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8:40 a.m.	Opening Remarks	<b>Karen Weiss, M.D.</b> Deputy Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), FDA
8:45 a.m.	Brief Overview FDA	<b>Lisa Mathis, M.D.</b> Office of New Drugs Associate Director Pediatric and Maternal Health Staff Office of New Drugs (OND), FDA
9:00 a.m.	Clarification questions from committee	
9:10 a.m.	Introduction to International Cooperation	<b>Murray Lumpkin, M.D., M.Sc.</b> Deputy Commissioner International and Special Programs, FDA
9:40 a.m.	European Medicines Directive	<b>Agnes Saint-Raymond, M.D.</b> Head of Sector Scientific Advice and Orphan Drugs Paediatric Medicinal Products, EMEA
10:10 a.m.	Clarification questions from the committee	
10:25 a.m.	Break	
10:40 a.m.	Overview: FDA and EMEA interactions	<b>Dianne Murphy, M.D.</b> Director, Office of Pediatric Therapeutics (OPT) Office of the Commissioner (OC), FDA
11:10 a.m.	Case Examples	<b>Jean Temeck, M.D.</b> Lead Medical Officer Office of Pediatric Therapeutics (OPT) Office of the Commissioner (OC), FDA
11:40 a.m.	Clarification questions from committee	
12:00 a.m.	Lunch	

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**AGENDA**

**April 16, 2008**

**(continued)**

- 1:00 p.m. Open Public Hearing
- 2:00 p.m. Prioritization of New Agents in Pediatric Oncology: A Perspective From CTEP/NCI **Malcolm Smith, M.D., Ph.D.**  
Associate Branch Chief, Pediatrics  
Cancer Therapy Evaluation Program, NCI
- 2:15 p.m. Overview of Pediatric Transatlantic Studies **Gregory H. Reaman, M.D.**  
Professor Of Pediatrics  
The George Washington University  
School of Medicine and Health Sciences
- 2:30 p.m. Clarification questions from committee and Discussion
- 3:30 p.m. Adjourn