Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

65th Meeting

Holiday Inn
Bethesda, Maryland

Agenda — March 16-17, 2000

8:30	Call to Order and Opening Remarks	Richard Schilsky, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	
9:00	**Pediatric Exclusivity Drug Development Plan**	Richard Pazdur, M.D. Director, Division of Oncology Drug Products

NDA 21-063, Eloxatin® (oxaliplatin), Sanofi Pharmaceuticals, Inc.

- indicated for the first-line treatment of patients with advanced colorectal cancer in combination with 5-FU based chemotherapy

9:15	**Sponsor Presentation**	Sanofi Pharmaceuticals, Inc.
	Introduction	Mark Moyer Director, Regulatory Affairs
	Background and Efficacy	Mace Rothenberg, M.D. Vanderbilt University
	Safety, Clinical Benefit and Conclusions	Daniel Haller, M.D. University of Pennsylvania
10:15	Questions from the Committee	
10:45	Break	
11:00	**FDA Presentation**	Steven Hirschfeld, M.D. FDA Reviewer
11:30	Questions from the Committee	
12:00	Committee Discussion and Vote	
	ODAC Discussants	Kim A. Margolin, M.D. ODAC Member
		David Kelsen, M.D. ODAC Member
12:30	Lunch	

1:30	Open Public Hearing	
	NDA 20-571/SE1-009, Camptosar® Injection (irinotecan hydrochloride injection), Pharmacia & Upjohn Company - indicated as a component of first-line therapy for patients with metastatic carcinoma of the colon or rectum	
1:45	**Sponsor Presentation**	**Pharmacia & Upjohn Company**
	Camptosar®: First-line Therapy of Metastatic Colorectal Cancer Background Pivotal Phase III Controlled Clinical Trials Study 0038/Study V303 Summary and Conclusions	Langdon Miller, M.D. Vice President Clinical Research Oncology for the Americas
2:45	Questions from the Committee	
3:15	Break	
3:30	**FDA Presentation**	Isagani Chico, M.D. FDA Reviewer
4:00	Questions from the Committee	
4:30	Committee Discussion and Vote	
	ODAC Discussants	Kathy Albain, M.D. ODAC Member Jaffer Ajani, M.D. ODAC Consultant
5:00	Adjourn	

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	Open Public Hearing	
	NDA 21-174, gemtuzumab zogamicin, Wyeth-Ayerst Laboratories	
	- indicated for the treatment of patients with CD33 positive acute myeloid leukemia in relapse	
8:45	**Sponsor Presentation**	Wyeth-Ayerst Laboratories
	Introduction	Barry D. Sickels Associate Director, Worldwide Regulatory Affairs
	Overview of Acute Myeloid Leukemia	Frederick Applebaum, M.D. Fred Hutchinson Cancer Research Center
	Design of Clinical Trials Safety and Efficacy Results	Mark Berger, M.D. Director, Clinical Research
	Benefit/Risk Assessment Conclusions	Matthew Sherman, M.D. Assistant Vice President, Clinical Research
9:45	Questions from the Committee	
10:15	Break	
10:30	**FDA Presentation**	Peter Bross, M.D. FDA Reviewer
11:00	Questions from the Committee	
	ODAC Discussants	Ellin Berman, M.D. ODAC Consultant
		Donna Przepiorka, M.D. ODAC Consultant
11:30	Committee Discussion and Vote	
12:00	Adjourn	