

Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee
Meeting Agenda
March 12-13, 2003

Versailles Ballroom
Holiday Inn
Bethesda, MD

74th Meeting

*Please note the agenda times listed are subject to
change as the meeting progresses*

March 12, 2003

8:00	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Conflict of Interest (COI) Statement & Introduction of Committee	Johanna Clifford, M.S., RN, BSN Executive Secretary, ODAC
8:15	Open Public Hearing	
8:45	Introduction – Accelerated Approval Process	Richard Pazdur, M.D., Director Ramzi Dagher, M.D., Medical Officer Division of Oncology Drug Products Center for Drug Evaluation & Research
9:15	Sponsor Presentation	Johnson & Johnson Pharmaceutical Research & Development, LLC
	<i>NDA 50-718 Doxil (doxorubicin hydrochloride)</i> <i>Indication: Treatment of Kaposi's sarcoma in AIDS patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy.</i>	
9:30	FDA Comments & ODAC Discussion	
10:15	<i>Break</i>	
10:30	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
	Sponsor Presentation	Johnson & Johnson, Pharmaceutical Research & Development, LLC
	<i>NDA 50-718/S-006 Doxil (doxorubicin hydrochloride)</i> <i>Indication: Treatment of metastatic ovarian cancer in patients with disease that is refractory to both paclitaxel and platinum-based chemotherapy regimens</i>	
10:45	FDA Comments & ODAC Discussion	
11:30	<i>Lunch</i>	
12:30	Open Public Hearing	
	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
1:00	Sponsor Presentation	Ligand Pharmaceuticals
	<i>BLA 97-1325/STN 103767 Ontak (deneluekin diftitox)</i> <i>Indication: Treatment of persistent or recurrent cutaneous T-Cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.</i>	

1:15	FDA Comments & ODAC Discussion	
2:00	<i>Break</i>	
2:15	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
	Sponsor Presentation	MedImmune Oncology, Inc.
	<i>NDA 20-221/S-002 Etyol (amifostine)</i>	
	<i>Indication: Reduction in cumulative renal toxicity associated with repeated administration of cisplatin in patients with non small cell lung cancer.</i>	
2:30	FDA Comments & ODAC Discussion	
3:15	Estimated Time of Adjournment	

March 13, 2003

8:00	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, BSN Executive Secretary, ODAC
8:15	Open Public Hearing	
8:45	Sponsor Presentation	Wyeth-Ayerst Laboratories, Inc.
	<i>NDA 21-174 Mylotarg (gemtuzumab ozogamicin)</i>	
	<i>Indication: Treatment of patients with CD33 positive acute myeloid leukemia is first relapse who are 60 years of age or who are not considered candidates for cytotoxic chemotherapy</i>	
9:00	FDA Comments & ODAC Discussion	
9:45	<i>Break</i>	
10:00	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN Executive Secretary, ODAC
	Sponsor Presentation	SkyePharma, Inc.
	<i>NDA 21-041 Depocyt (cytarabine)</i>	
	<i>Indication: Intrathecal treatment of lymphomatous meningitis</i>	
10:15	FDA Comments & ODAC Discussion	
11:00	<i>Lunch</i>	
12:00	Open Public Hearing	
12:30	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN Executive Secretary, ODAC

Sponsor Presentation

Pharmacia Corporation

NDA 21-156 Celebrex (celecoxib)

Indication: Reduction in number of adenomatous colorectal polyps in familial adenomatous polyposis patients.

12:45 FDA Comments & ODAC Discussion

1:30 *Break*

1:45 COI Statement and Introduction of New Participants Johanna Clifford, M.S., RN, BSN
Executive Secretary, ODAC

Sponsor Presentation

Schering-Plough Corporation

NDA 21-029 Temodar (temozolomide)

Indication: Treatment of adult patients with refractory anaplastic astrocytoma

2:00 FDA Comments & ODAC Discussion

2:45 Introduction of Questions and Committee Discussion

4:00 Estimated Time of Adjournment
