

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ONCOLOGIC DRUGS ADVISORY COMMITTEE MEETING
DRAFT AGENDA

December 16, 2003
Advisors and Consultants Conference Room, Rockville, Maryland

8:00 a.m.	Call to Order	Donna Przepiorka, M.D., Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, BSN Executive Secretary, ODAC

8:10 a.m.	Opening Remarks
8:15 a.m.	General Regulatory Background
8:25 a.m.	Endpoints for Past Approvals
8:35 a.m.	Time to Progression Endpoint
8:55 a.m.	Challenges in Oncology Clinical Trials
9:25 a.m.	Clarification Questions to Presenters
9:35 a.m.	<i>Break</i>
9:50 a.m.	Open Public Hearing
10:20 a.m.	Questions for Discussion
12:00 p.m.	<i>Lunch</i>
1:00 p.m.	NSCLC Regulatory Background
1:20 p.m.	FDA/ASCO NSCLC Workshop Summary .
1:50 p.m.	Patient Reported Outcomes in NSCLC
2:05 p.m.	Clarification Questions to Presenters
2:15 p.m.	<i>Break</i>
2:30 p.m.	Open Public Hearing
3:00 p.m.	Questions for Discussion
5:00 p.m.	Adjourn