Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH
Oncologic Drugs Advisory Committee

Meeting Agenda

July 27, 2004

8:30 a.m.	Call to Order and Opening Remarks Introduction of Committee	Otis Brawley, M.D. Guest Chair, ODAC
	Conflict of Interest (COI) Statement	Johanna Clifford, M.S.,RN Executive Secretary, ODAC

The committee will discuss New Drug Application (NDA) 21-677, ALIMTA (pemetrexed) Eli Lilly & Company, proposed indication for single-agent treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy.

8:45 a.m.	Introduction	Richard Pazdur, M.D., Director Division of Oncology Drug Products Center for Drug Evaluation & Research, FDA
9:00 a.m.	**Sponsor Presentation**	
	Introduction and Objectives of the Presentation	Paolo Paoletti, M.D. Eli Lilly and Company
	Background on Non-Small Cell Lung Cancer Second Line	Frances Shepherd, M.D. Princess Margaret Hospital University of Toronto
	Alimta Development	Roy Herbst, M.D., Ph.D. M.D. Anderson Cancer Center University of Texas
	Clinical Efficacy from the Pivotal Study JMEI	Paul Bunn, M.D. University of Colorado Cancer Center
	Safety Profile from the Pivotal Study JMEI	Richard Gralla, M.D. Multinational Association of Supportive Care in Cancer
	Overall Conclusions	Paul Bunn, M.D.
10:00 a.m.	**FDA Presentation**	
	Clinical Review	Martin H. Cohen, M.D., Medical Officer Division of Oncology Drug Products, FDA
	Statistical Review	Yong-Cheng Wang, Ph.D., Statistical Reviewer Division of Oncology Drug Products, FDA
10:45 a.m.	Break	
11:00 a.m.	Open Public Hearing	
12:00 p.m.	Questions from the Committee	
12:30pm.	*Lunch*	
1:30 p.m.	ODAC Discussion	
4:00 p.m.	Estimated Time of Adjournment	