Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

72nd Meeting

Holiday Inn
8777 Georgia Avenue
Silver Spring, Maryland

Agenda — September 24, 2002

8:30	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
8:45	Open Public Hearing	

NDA 21-399, IRESSA® (gefitinib), AstraZeneca Pharmaceuticals LP

- indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer who have previously received platinum-based chemotherapy

9:45	**Sponsor Presentation**	**AstraZeneca Pharmaceuticals LP**
	IRESSA® (ZD1839) Monotherapy for NSCLC Introduction and Rationale for Clinical Development	George Blackledge, M.D., Ph.D., MB, F.R.C.P. Clinical Vice President of Oncology
	Recurrent Non-Small Cell Lung Cancer	Frances A. Shepherd, M.D., F.R.C.P.C. Director, Division Medical Oncology University of Toronto
	IRESSA® (ZD1839) Efficacy	Ronald B. Natale, M.D. Medical Director Cedars Sinai Comprehensive Cancer Center
	IRESSA® Safety Profile	Alan B. Sandler, M.D., F.A.C.P. Associate Professor of Medicine Vanderbilt University

10:45	Break	
11:00	**FDA Presentation**	
	Introduction and Regulatory Background	Grant Williams, M.D. Deputy Director Division of Oncology Drug Products, FDA
	Review of the Clinical Trials	Martin Cohen, M.D. Medical Reviewer, FDA
	Statistical Analysis	Rajeshwari Sridhara, Ph.D. Statistical Reviewer, FDA
	Summary	Grant Williams, M.D.
11:45	Questions from the Committee	
12:45	Lunch	
1:45	Committee Discussion and Vote	
4:00	Estimated Time of Adjournment	