Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

71th Meeting
Holiday Inn
8120 Wisconsin Avenue
Bethesda, Maryland

Tentative Agenda — February 27, 2002

8:00	Call to Order and Opening Remarks	Stacy Nerenstone, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	

Trial Design Considerations and Appropriate Patient Populations for Studies of Investigational Agents for Adjuvant Therapy of Melanoma Given the Availability of an Approved agent for this Indication

9:00 Efficacy and Safety of Adjuvant High-dose Interferon for High-risk Melanoma: ECOG and Intergroup Trial

John M. Kirkwood, MD - University of Pittsburgh Cancer Institute

Cure Rate Models and Adjuvant Trial Design for ECOG Studies in the Past, Present and Future

Joseph G. Ibrahim, PhD - Harvard School of Public Health

9:45 FDA presentation

10:15 Break

10:30 Committee Discussion

12:00 Lunch

1:00 Open Public Hearing

Appropriate Study Design and Control for the Proposed Phase 3 Trial of Investigational New Drug (IND) 2885, Melacine® (melanoma vaccine), Corixa Corporation, for adjuvant treatment of melanoma

1:15	Sponsor Presentation	Corixa Corporation
	Melacine® vaccine as adjuvant therapy for Stage II melanoma: Issues for further development and regulatory approval	Martin A. Cheever, M.D. Vice President, Medical Affairs

2:15	Committee Discussion
5:00	Adjourn