

**Food and Drug Administration
Center for Drug Evaluation and Research**

Oncologic Drugs Advisory Committee

67th Meeting

Holiday Inn - Bethesda, Maryland

Tentative Agenda

June 7, 2001

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	

Single Patient Use of Non-approved Oncology Drugs and Biologics

9:00	Introduction	
	Summary of Regulatory and Industry Considerations	Grant Williams, M.D. Medical Team Leader, DODP, CDER
9:20	Summary of the Ethical Considerations	Sarah Taylor, M.D. ODAC Member
9:40	Perspective from the Patient Advocacy Community	Jody Pelusi, F.N.P., Ph.D. ODAC Member
10:00	Break	
10:15	Committee Discussion	
	ODAC Discussants	Sarah Taylor, M.D. ODAC Member Jody Pelusi, F.N.P., Ph.D. ODAC Member
12:00	Adjourn	