

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

Oncologic Drugs Advisory Committee

70th Meeting

Advisors and Consultants Staff Conference Room

5630 Fishers Lane

Rockville, Maryland

Tentative Agenda

January 31, 2002

8:30	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	
	Ann E. Fonfa – The Annie Appleseed Project (letter)	
	sNDA 21-386, Zometa ® (zoledronic acid for injection), Novartis Pharmaceuticals Corporation	
	- indicated for the treatment of bone metastases in patients with multiple myeloma, breast cancer, prostate cancer and other solid tumors	
9:00	Sponsor Presentation Introduction; Study 010	Novartis Pharmaceuticals Corporation
10:00	FDA Presentation Study 010	Grant Williams, M.D. Medical Team Leader Division of Oncology Drug Products
10:20	Questions from the Committee	
10:50	Break	
11:05	Sponsor Presentation Introduction; Studies 039 and 011	Novartis Pharmaceuticals Corporation
11:50	FDA Presentation Studies 039 and 011	Amna Ibrahim, M.D. Medical Officer Division of Oncology Drug Products
	Safety Review	Nancy Scher, M.D. Medical Officer Division of Oncology Drug Products
12:30	Questions from the Committee	
1:00	Lunch	

1:45	Open Public Hearing
2:15	Committee Discussion and Vote
4:00	Adjourn