

DRAFT AGENDA

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

June 2, 2006

10:00 a.m.	Call to Order	Silvana Martino, D.O.
	Introduction of Committee	Acting Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.Sc., RN, Executive Secretary, ODAC
10:15 a.m.	Opening Remarks & ODAC Member Appreciation	Richard Pazdur, M.D., Director Office of Oncology Drug Products, FDA

The committee will discuss the following new drug application (NDA) 21-986, proposed trade name Sprycel™ (dasatinib) tablets, Bristol-Myers Squibb Company, with proposed indications for (1) the treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy including imatinib, and (2) the treatment of adults with Philadelphia chromosome–positive acute lymphoblastic leukemia and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy.

10:25 a.m.	<u>Sponsor Presentation</u>	Bristol Myers Squibb & Co.
11:10 a.m.	<u>FDA Presentation</u>	
11:45 a.m.	<i>Questions from the Committee</i>	
12:15 p.m.	Break	
12:30 p.m.	Open Public Hearing	
1:30 a.m.	<i>Questions to the ODAC and ODAC Discussion</i>	
2:00 p.m.	<i>Adjourn</i>	