

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTIVIRAL DRUGS ADVISORY COMMITTEE (AVAC) MEETING

DRAFT AGENDA

May 13, 2003

Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, MD

NDA 21-567 and 21-568, Reyataz™ (atazanavir sulfate) capsules and powder for oral use, Bristol-Myers Squibb Company, proposed for the treatment of HIV infection in combination with other antiretroviral agents

8:00 a.m.	Call to Order	Roy M. Gulick, M.D., M.P.H. Chair, AVAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AVAC
8:15 a.m.	Opening Remarks	Debra B. Birnkrant, M.D. Director Division of Antiviral Drug Products FDA
8:30 a.m.	Evaluation of QT Interval	FDA Consultant
8:45 a.m.	Sponsor Presentation	Bristol-Myers Squibb Company
	Introduction	Elliott Sigal, M.D., Ph.D. Sr. Vice President, Global Clinical and Pharmaceutical Development
	Clinical Development Program and Clinical Trial Results	Steven M. Schnittman, M.D. Vice President, Global Development
	Cardiac Electrophysiology Evaluations	John H. Lawrence, M.D. Executive Director Clinical Design and Evaluation
	Characterization of Hyperbilirubinemia	Michael Giordano, M.D. Group Director Clinical Design and Evaluation
	Characterization of Lipid Profile	Michael Giordano, M.D. Group Director Clinical Design and Evaluation
	Overall Risk/Benefit and Conclusions	Elliott Sigal, M.D., Ph.D.

9:45 a.m. Questions from the Committee

10:00 a.m. Break

10:15 a.m. **FDA Presentation**

Kendall Marcus, M.D.
Medical Officer
Division of Antiviral Drug Products

Lisa Naeger, Ph.D.
Microbiology Reviewer
Division of Antiviral Drug Products

Tom Hammerstrom, Ph.D.
Statistical Reviewer
Division of Biometrics III

11:15 a.m. Questions from the Committee

12:00 p.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee/Questions for Discussion

Debra B. Birnkrant, M.D.

5:00 p.m. Adjourn