

**Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**Antiviral Drugs Advisory Committee**

**May 19, 2005**

*Hilton  
620 Perry Parkway  
Gaithersburg, Maryland*

**The Antiviral Drugs Advisory Committee will discuss new drug application (NDA) 021-814, proposed tradename Aptivus (Tipranavir) 250 milligrams (mg) capsules, Boehringer Ingelheim Pharmaceuticals, Inc., indicated for the treatment of patients with HIV.**

8:00	Call to Order and Opening Remarks	Janet Englund, M.D. Chair
	Introduction of Committee	
	Conflict of Interest Statement	Anuja Patel, M.P.H. Executive Secretary, FDA
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8:10	Overview of Issues	Debra B. Birnkrant, M.D. Director, Division of Antiviral Drug Products (DAVDP)
8:15	<b><u>Sponsor Presentations</u></b> <b>Boehringer Ingelheim Pharmaceuticals, Inc.</b>	
	• Introduction	Burkhard Blank, M.D. Senior Vice President Medicine/DRA
	• Tipranavir Development	Douglas Mayers, M.D. International Head, Therapeutic Area Virology
	• Efficacy and Drug: Drug Interactions	Scott McCallister, M.D. Global Medical Team Leader, TPV
	• Safety	Christopher Corsico, M.D. Head, Drug Surveillance and Information
	• Resistance	Douglas Mayers, M.D. International Head, Therapeutic Area Virology
	• Potential Utility of Tipranavir In Current Clinical Practice	Daniel Kuritzkes, M.D. Director of AIDS Research, Brigham and Women's Hospital, Division of AIDS, Associate Professor of Medicine, Harvard Medical School
	• Conclusions	Burkhard Blank, M.D. Senior Vice President Medicine/DRA

