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 Introduction of Committee Conflict of Interest Statement	Janet Englund, M.D. Chair Anuja Patel, M.P.H. Executive Secretary, FDA
8:10	Overview of Issues	Debra B. Birnkrant, M.D. Director, Division of Antiviral Drug Products (DAVDP)
8:15	 Sponsor Presentations Boehringer Ingelheim Pharmaceuticals, Introduction Tipranavir Development Efficacy and Drug: Drug Interactions Safety Resistance Potential Utility of Tipranavir In Current Clinical Practice 	Burkhard Blank, M.D. Senior Vice President Medicine/DRA Douglas Mayers, M.D. International Head, Therapeutic Area Virology Scott McCallister, M.D. Global Medical Team Leader, TPV Christopher Corsico, M.D. Head, Drug Surveillance and Information Douglas Mayers, M.D. International Head, Therapeutic Area Virology 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

9:30 **Break** 9:45 **FDA Presentations Division of Antiviral Drug Products Efficacy Evaluation** Rafia Bhore, Ph.D. Statistical Reviewer **Resistance Evaluation** Lisa Naeger, Ph.D. Senior Microbiology Reviewer Exposure-Response Data Jenny J. Zheng, Ph.D. Pharmacometrics Reviewer **Drug Interactions** Yuanchao (Derek) Zhang, Ph.D. Clinical Pharmacology and Biopharmaceutics Reviewer Safety Profile and Conclusions Andrea James, M.D. Medical Reviewer Questions from the Committee to the Sponsor and FDA 11:15 Lunch Noon 1:00 **Awards Presentation** Open Public Hearing 2:00 Continue Discussion and Questions to the Committee 5:00 Adjourn