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

Antiviral Drugs Advisory Committee

March 11, 2005

Hilton
620 Perry Parkway
Gaithersburg, Maryland

The Antiviral Drugs Advisory Committee will discuss new drug applications (NDAs) 21-797 and 21-798, entecavir tablets and entecavir oral solution, respectively, Bristol-Myers Squibb Company, proposed for the treatment of patients with chronic hepatitis B infection (HBV).

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

8:10	Overview of Issues	Debra B. Birnkrant, M.D. Director, Division of Antiviral Drug Products (DAVDP)
8:15	**<u>Sponsor Presentations</u>** **Bristol-Myers Squibb Company**	
	• Introduction	Elliott Sigal, M.D., Ph.D. Chief Scientific Officer & President, Pharmaceutical Research Institute
	• Background	Richard Wilber, M.D. Vice President, Global Development
	• Nonclinical Safety	Lois Lehman-McKeeman, Ph.D. Distinguished Research Fellow, Discovery Toxicology
	• Clinical/Efficacy and Safety	Helena Brett-Smith, M.D. Director, Infectious Diseases Clinical Research
	• Resistance	Richard Colonno, Ph.D. Vice President, Infectious Diseases Drug Discovery
	• Benefit vs. Risk Assessment	Donna Morgan Murray, Ph.D. Executive Director, Global Regulatory Sciences
9:30	Questions from the Committee	

9:45	**Break**	
10:00	**<u>FDA Presentations</u>** **Division of Antiviral Drug Products**	
	• Carcinogenicity Issues	James G. Farrelly, Ph.D. Pharmacology Team Leader, DAVDP
	• Clinical Issues	Linda L. Lewis, M.D. Lead Medical Officer, DAVDP
11:00	Discussion	
Noon	**Lunch**	
1:00	Open Public Hearing	
2:00	Continue Discussion and Questions to the Committee	
5:00	**Adjourn**	