

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

AGENDA
August 6, 2002

Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

NDA 21-449, adefovir dipivoxil tablets, Gilead Sciences, Inc., proposed for treatment of chronic hepatitis B infection

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
8:10 a.m.	Opening Remarks	Debra B. Birnkrant, M.D. Director Division of Antiviral Drug Products FDA
8:15 a.m.	Sponsor Presentation	Gilead Sciences, Inc.
	Evaluation of Liver Histology in Clinical Trials for Chronic Viral Hepatitis	Zachary D. Goodman, M.D., Ph.D. Chief, Division of Hepatic Pathology Armed Forces Institute of Pathology
	Introduction Chronic Hepatitis B Pre-Clinical Clinical Pharmacokinetics	Alan Taylor, Ph.D. Vice President, Regulatory Affairs Gilead Sciences
	Clinical Efficacy and Safety Pivotal Studies Supportive Studies Further Studies	Carol Brosgart, M.D. Vice President, Clinical Research Gilead Sciences
9:45 a.m.	Break	
10:15 a.m.	FDA Presentation	Rafia Bhore, Ph.D. Mathematical Statistician Division of Antiviral Drug Products
		Tan T. Nguyen, M.D., Ph.D. Medical Officer Division of Antiviral Drug Products
11:15 a.m.	Discussion of Presentations	

12:00 p.m. Lunch

1:00 p.m. Open Public Hearing

Larry Kramer

Rochelle Yedvarb

Elias Anastasopoulos

Alan P. Brownstein, M.P.H. – American Liver Foundation

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

5:00 p.m. Adjourn