

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

**AGENDA**  
October 3, 2001

The Town Center Hotel –Silver Spring, Maryland

NDA 21-356, Viread™ (tenofovir disoproxil fumarate) Tablets, Gilead Sciences, Inc., proposed for the treatment of human immunodeficiency virus (HIV) infection.

8:30 a.m.	Call to Order/Welcome	Roy M. Gulick, M.D., M.P.H. Chair, AVAC
	Introduction of Committee	
8:35 a.m.	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AVAC
8:45 a.m.	<b>Introduction/Opening Remarks</b>	Debra Birnkrant, M.D. Acting Director Division of Antiviral Drug Products, FDA
9:00 a.m.	<b>Sponsor Presentation</b>	Gilead Sciences, Inc.
	Overview of Development Program	Norbert Bischofberger, Ph.D. Executive Vice President Research and Development
	Clinical Trial Results	Jay Toole, M.D., Ph.D. Vice President Clinical Research
	Phase IV Plans and Concluding Remarks	Norbert Bischofberger, Ph.D.
9:45 a.m.	<b>FDA Presentation</b>	Kimberly Struble, Pharm.D. Senior Regulatory Review Officer Division of Antiviral Drug Products, FDA
		James Farrelly, Ph.D. Pharmacology Supervisor Division of Antiviral Drug Products, FDA
10:30 a.m.	Break	
10:45 a.m.	Questions to Presenters	
12:00 p.m.	Lunch	

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1:00 p.m.      Open Public Hearing

Yvette Delph, M.D. - Treatment Action Group (TAG)  
Brett Grodeck – Santa Monica, California  
Ben Cheng – Project Inform

2:00 p.m.      Questions to Committee  
Committee Discussion

5:00 p.m.      Adjourn