FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antiviral Drugs Advisory Committee (AVDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
May 10, 2012

DRAFT AGENDA

The committee will discuss an efficacy supplement for new drug application (NDA) 21-752, TRUVADA® (emtricitabine/tenofovir disoproxil fumarate), submitted by Gilead Sciences, Inc. The supplemental application proposes an indication for Pre-Exposure Prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

8:00 a.m.	Call to Order and Introduction of Committee	**Judith Feinberg, M.D., FACP, FIDSA** Acting Chairperson, AVDAC
	Conflict of Interest Statement	**Yvette Waples, Pharm.D.** Acting Designated Federal Officer, AVDAC
8:05 a.m.	Opening Remarks	**Debra Birnkrant, M.D.** Director, Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**GUEST SPEAKER PRESENTATION**	
	Epidemiology and Behavioral Interventions	
8:35 a.m.	**CDC PRESENTATION**	
	Non-clinical Data and CDC Clinical Trials	
8:55 a.m.	Clarifying Questions from Committee	
9:10 a.m.	**SPONSOR PRESENTATIONS**	**Gilead Sciences, Inc.**
	Truvada Overview	
	Pre-Exposure Prophylaxis (PrEP) Initiative	
	Antiretroviral PrEP for HIV-1 Prevention Among Heterosexual Men and Women: the Partners PrEP Study	
	Truvada for PrEP	
	Closing Comments	
10:40 a.m.	Clarifying Questions from Committee	
10:55 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

11:10 a.m.	**NIH PRESENTATION**	
	VOICE Trial	
11:20 a.m.	**FDA PRESENTATIONS**	
	Safety and Efficacy of Submitted Clinical Trials	
	Risk Evaluation and Mitigation Strategy (REMS)	
12:10 p.m.	Clarifying Questions from the Committee	
12:40 p.m.	**LUNCH**	
1:40 p.m.	Open Public Hearing	
3:40 p.m.	**BREAK**	
3:55 p.m.	Charge to the Committee	**Debra Birnkrant, M.D.**
	Questions to the Committee and Committee Discussion	
6:30 p.m.	**ADJOURNMENT**	