

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
August 7, 2019

DRAFT AGENDA

The committee will discuss supplemental new drug application (sNDA) 208215, supplement 12, DESCOPY (emtricitabine 200 milligrams (mg) and tenofovir alafenamide 25 mg tablets), submitted by Gilead Sciences, Inc., proposed for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection among individuals who are HIV-negative and at risk for HIV.

8:30 a.m.	Call to Order and Introduction of Committee	Lindsey Baden, MD Chairperson, AMDAC
8:35 a.m.	Conflict of Interest Statement	Lauren Tesh Hotaki, PharmD, BCPS, BCIDP Designated Federal Officer, AMDAC
8:40 a.m.	FDA Opening Remarks	Jeffrey Murray, MD Deputy Director Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:50 a.m.	APPLICANT PRESENTATIONS	Gilead Sciences, Inc.
	Introduction	Diana Brainard, MD Senior Vice President HIV and Emerging Viruses Gilead Sciences, Inc.
	DISCOVER Study Design, Treatment Population, and Efficacy Results	Scott McCallister, MD Executive Director HIV and Emerging Viruses Gilead Sciences, Inc.
	DISCOVER Safety and Extrapolations	Moupali Das, MD, MPH Executive Director HIV and Emerging Viruses Gilead Sciences, Inc.
	Clinical Context	Richard Elion, MD Director of Research Washington Health Institute Clinical Professor of Medicine George Washington University

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DRAFT AGENDA (cont.)

10:15 a.m. **BREAK**

10:25 a.m. Clarifying Questions

11:05 a.m. **FDA PRESENTATION**

NDA 208215/S12 – Descovy PrEP

Peter Miele, MD
Medical Officer
DAVP, OAP, OND, CDER, FDA

11:45 a.m. Clarifying Questions

12:25 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion (cont.)

4:30 p.m. **ADJOURNMENT**