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.

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| 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                 | Susan Buchbinder, M.D.  
Director, HIV Research Section  
San Francisco Department of Public Health  
San Francisco, California |
| 8:35 a.m. | CDC PRESENTATION                           | Lynn A. Paxton, M.D., M.P.H.  
Captain, United States Public Health Service  
Medical Epidemiologist, Epidemiology Branch  
Division of HIV/AIDS Prevention  
Center for Disease Control and Prevention (CDC)  
Atlanta, Georgia |
| 8:55 a.m. | Clarifying Questions from Committee        |                                                                            |
| 9:10 a.m. | SPONSOR PRESENTATIONS                      | Gilead Sciences, Inc.  
Andrew Cheng, M.D., Ph.D.  
Senior Vice President HIV Therapeutics & Development Operations  
Gilead Sciences, Inc. |
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<td>10:40 a.m.</td>
<td>Clarifying Questions from Committee</td>
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<td>10:55 a.m.</td>
<td><strong>BREAK</strong></td>
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<td>11:10 a.m.</td>
<td><strong>NIH PRESENTATION</strong></td>
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|           | VOICE Trial                                | **Jeanna M. Piper, M.D.**  
Senior Medical Officer, Division of AIDS  
National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIH)  
Bethesda, Maryland |
|           | Pre-Exposure Prophylaxis (PrEP) Initiative | **Robert M. Grant, M.D., M.P.H.**  
Senior Investigator, Gladstone Institute of Virology & Immunology  
Professor of Medicine  
University of California, San Francisco |
|           | Antiretroviral PrEP for HIV-1 Prevention   | **Connie Celum, M.D., M.P.H.**  
Professor, Departments of Global Health and Medicine  
Adjunct Professor, Department of Epidemiology  
Director, International Clinical Research Center  
University of Washington |
|           | Among Heterosexual Men and Women: the      | **Jared Baeten, M.D., Ph.D.**  
Associate Professor, Departments of Global Health and Medicine  
Adjunct Associate Professor, Department of Epidemiology  
University of Washington |
|           | Partners PrEP Study                        | **Andrew Cheng, M.D., Ph.D.**  
Senior Investigator, Gladstone Institute of Virology & Immunology  
Professor of Medicine  
University of California, San Francisco |
|           | Truvada for PrEP                           | **John W. Mellors, M.D.**  
Chief, Division of Infectious Diseases  
University of Pittsburgh |
|           | Closing Comments                           |                                                                              |
AGENDA (cont.)

11:20 a.m.  **FDA PRESENTATIONS**

Truvada: Pre-exposure Prophylaxis (PrEP) Indication for Prevention of Sexually Acquired HIV-1

Peter Miele, M.D.
Medical Officer
DAVP, OAP, OND, CDER, FDA

Proposed Risk Evaluation and Mitigation Strategy (REMS) for Truvada for a Pre-exposure Prophylaxis (PrEP) Indication for Prevention of HIV-1 Infection

Carolyn L. Yancey, M.D.
Medical Officer
Division of Risk Management
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

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**