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

***Antiviral Drugs Advisory Committee (AVDAC) Meeting***
DoubleTree by Hilton Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, Maryland
May 11, 2012

**DRAFT AGENDA**

*The committee will discuss a new drug application (NDA) 203100, for a fixed-dose combination tablet of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, submitted by Gilead Sciences, Inc. The application proposes an indication for the treatment of HIV-1 infection in adults who are antiretroviral naïve or have no known substitutions associated with resistance to the individual components.*

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| 8:00 a.m. | Call to Order and Introduction of Committee | **Yoshihiko Murata, M.D., Ph.D.**<br>Acting Chairperson, AVDAC |
| 8:05 a.m. | Conflict of Interest Statement | **Yvette Waples, Pharm.D.**<br>Acting Designated Federal Officer, AVDAC |
| 8:15 a.m. | Opening Remarks | **Linda Lewis, M.D.**<br>Medical Team Leader<br>Division of Antiviral Products (DAVP)<br>Office of Antimicrobial Products (OAP)<br>Office of New Drugs (OND), CDER, FDA |
| 8:30 a.m. | **SPONSOR PRESENTATIONS** | **Gilead Sciences, Inc.** |
| | Introduction | |
| | Early Clinical Development | |
| | Clinical Program, Efficacy and Safety | |
| | Benefit/Risk | |
| 9:30 a.m. | Clarifying Questions from Committee | |
| 10:00 a.m. | **BREAK** | |
| 10:15 a.m. | **FDA PRESENTATION** | |
| | NDA 203100 - Summary of FDA Review | |
| 11:00 a.m. | Clarifying Questions from the Committee | |
| 11:30 a.m. | **LUNCH** | |

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**DRAFT AGENDA (cont.)**

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| 12:30 p.m. | Open Public Hearing | |
| 1:30 p.m. | Charge to the Committee | **Linda Lewis, M.D.** |
| | Questions to the Committee and Committee Discussion | |
| 3:00 p.m. | **BREAK** | |
| 3:15 p.m. | Questions to the Committee and Committee Discussion | |
| 5:00 p.m. | **ADJOURNMENT** | |