**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 Questions to the Committee**

1. **DISCUSSION:** Please comment on the safety profile of elvitegravir/cobicistat/emtricitabine/ tenofovir disoproxil fumarate, focusing on proximal tubulopathy and other renal adverse events leading to subject discontinuation.

2. **VOTE:** Considering the overall risks and benefits, do the available data support approval of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate as a complete regimen for treatment of HIV-1 infection in treatment-naïve adults?

    a. If no, what additional studies are recommended?

    b. If yes, proceed with the remaining questions.

3. **DISCUSSION:** Please comment on whether there are additional measures needed to improve renal safety in patients receiving elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate. As part of your discussion, please comment on the following:

    a. Would additional laboratory monitoring (e.g. urine dipstick testing for protein and glucose) potentially improve renal safety? Does use in patients with baseline glycosuria and proteinuria warrant separate recommendations?

    b. Would renal safety be enhanced by monitoring renal function in all patients as opposed to only patients with renal impairment or at risk of renal impairment?

    c. Should laboratory cutoffs be provided to help distinguish the effect of cobicistat on serum creatinine and creatinine clearance from genuine renal dysfunction? If yes, please comment on specific parameters, including, but not limited to the Applicant's current proposal.

4. **DISCUSSION:** Please discuss any post marketing studies needed to further define risks or optimal use of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate.