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 Questions to the Committee

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1. Does the current application support a favorable risk-benefit assessment adequate to approve TRUVADA® for a PrEP indication in:
    a. **VOTE:** HIV-uninfected men who have sex with men (MSM)?
    b. **VOTE:** HIV-uninfected partners in serodiscordant couples?
    c. **VOTE:** Other individuals at risk for acquiring HIV through sexual activity?

    If no, what additional data are needed to support a favorable risk-benefit assessment adequate to approve TRUVADA for this indication for the populations listed above?

    If yes, please address the following topics:

2. **DISCUSSION:** Discuss laboratory testing during administration of TRUVADA for a PrEP indication.
    a. How frequently should HIV testing be recommended?
    b. Which safety assessments should be recommended and how frequently?

3. **DISCUSSION:** Please comment on the Applicant's proposed Risk Evaluation and Mitigation Strategy (REMS).
    a. Prescriber education program including appropriate target prescribers.
    b. What metrics could be considered in the REMS assessment in addition to prescriber and user surveys, number of prescribers trained and drug usage data?

4. **DISCUSSION:** What postmarketing studies should be conducted (e.g. emergence of drug resistance, behavioral changes, patterns of use, safety assessments)?

5. **DISCUSSION:** Please comment on whether the currently available evidence on the efficacy of TRUVADA for a PrEP indication make the conduct of placebo-controlled trials of primary HIV prevention unethical.