FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee
The Inn & Conference Center, University of Maryland University College, Adelphi, MD
October 8, 2009
Questions to the Committee

The Division is convening this meeting to solicit the committee's comments on the following questions:

1) Please discuss the use of a reanalysis of the efficacy data, using the Enhanced Sensitivity Trofile™ Assay, to support efficacy for a treatment naïve indication of maraviroc (MVC).

2) Please discuss the relative increase in virologic resistance that was observed with MVC and compare this with the relative increase in adverse events with efavirenz.

3) Do the safety, efficacy, and resistance data presented support the approval of MVC in treatment-naïve HIV-1 infected patients with chemokine (C-C motif) receptor 5 (CCR5) -tropic only virus?

   VOTE: Yes: No: Abstain:

4) Please comment on any additional data that the sponsor should provide to further characterize the safety and efficacy profile of MVC in treatment-naïve patients.

5) Please discuss the MVC exposure-response data, and whether the magnitude of benefit would justify therapeutic drug monitoring.