FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING

QUESTIONS TO THE COMMITTEE

October 3, 2001

The Town Center Hotel –Silver Spring, Maryland

NDA 21-356, Viread™ (tenofovir disoproxil fumarate) Tablets, Gilead Sciences, Inc., proposed for the treatment of human immunodeficiency virus (HIV) infection.

1. In what patient population has tenofovir demonstrated efficacy and safety? For what indication should tenofovir be recommended, e.g., for the treatment of HIV infection or for the treatment of HIV infection in patients who have received prior antiretroviral therapy?

2. Please provide your assessment of the preclinical and clinical data with regard to bone effects. Are there additional non clinical or clinical studies that the applicant should conduct to further evaluate tenofovir associated bone abnormalities?

3. Please provide comments on the clinical resistance analyses conducted during the development of tenofovir. Also please provide recommendations for the types of clinical virology analyses that should be conducted for future antiretroviral drug development and suggestions for type of resistance data/analyses warranting display in package inserts.

4. Please provide comments on the applicant's proposed second study for traditional approval. Please also provide comments for other study designs or patient populations that should be studied as phase 4 commitments.