Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Antiviral Drugs Advisory Committee

March 11, 2005

FINAL QUESTIONS

Question 1:

How would you assess the risk-benefit of ETV in the context of the available clinical safety, efficacy, resistance, and non-clinical carcinogenicity data?

Question 2:

A. Does the risk-benefit assessment for entecavir support the approval of entecavir for the treatment of chronic HBV in adult patients?

B. If the answer to #2A is no, what information would be needed to support a resubmission?

Question 3:

A. If the answer to #2A is yes, discuss whether the results of the rodent carcinogenicity studies should impact the Indication and Usage section of product labeling.

B. Based on the available data, discuss the potential role of entecavir in the HBV treatment armamentarium.

Question 4:

A. Assess the potential risks and benefits of proceeding with development of entecavir for the treatment of chronic HBV in pediatric patients.

B. What, if any, additional information is needed in order to proceed?

Question 5:

Discuss the applicant's proposed pharmacovigilance plan to address human cancer risk, including comments on the design of the proposed large simple study.

Question 6

Are there other issues that you would like to see addressed through post-marketing commitments?