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

QUESTIONS TO THE COMMITTEE

May 13, 2003

Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, MD

NDA 21-567 and 21-568, Reyataz™ (atazanavir sulfate) capsules and powder for oral use, Bristol-Myers Squibb Company, proposed for the treatment of HIV infection in combination with other antiretroviral agents

1. Do the efficacy and safety of atazanavir support its approval for the treatment of HIV infection? As part of your discussion please comment on:

   - Treatment effects seen in naïve and experienced patients
   - Hyperbilirubinemia observed in clinical trials
   - The effect of atazanavir on the PR and QT intervals

2. If atazanavir is recommended for approval, does its safety profile warrant additional clinical or laboratory monitoring?

3. Does the effect of atazanavir on lipid parameters offer patients a clinically significant advantage over other treatment options?

4. Based on the resistance data, what recommendations would you have regarding its use in naïve and experienced patients?

5. Please provide recommendations for any Phase 4 studies of atazanavir.