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

Questions for the Antiviral Drugs Advisory Committee

1) Do the available data support accelerated approval of raltegravir for the treatment of HIV-1 infection?

   If no, what additional studies are recommended?
   If yes, please answer Question 2.

2) Raltegravir proposed indication – "In combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy."

   a) Do the data from Protocols 005, 018 and 019 support the proposed indication for treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy?
   b) Should the indication be restricted to the population enrolled in the pivotal studies, specifically patients with few or no remaining treatment options?

3) Please discuss the pros and cons of the following potential treatment strategies in future clinical trials used to support drug development, and more specifically, if you would like to see these studies conducted using raltegravir as post-marketing commitments.
   a) Nucleoside-sparing regimens in treatment-naïve patients using either two-drug/two-class or three-drug/three-class regimens
   b) Nucleoside-sparing regimens or three-drug/three class regimens in first treatment failure patients

4) What additional studies would you like to see undertaken as post-marketing commitments?

5) What strategies would help increase study enrollment of women and minorities?