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

QUESTIONS TO THE COMMITTEE

December 12, 2001

Holiday Inn –Bethesda, Maryland

Topic: An update on the approval of BLA 103949/5002, PEG-Intron™ (peginterferon alfa-2b) Powder for Injection, indicated for use alone or in combination with Rebetol (ribavirin, USP) for the treatment of chronic hepatitis C in patients with compensated liver disease who have not been previously treated with interferon alpha and are at least 18 years of age.

1. Please comment on the nature and design of the postmarketing studies outlined in the August 7, 2001 Approval Letter.

2. Please comment on other issues regarding Peginterferon and ribavirin that could be evaluated in further studies.