**Gastrointestinal Drugs Advisory Committee**

**QUESTIONS**
June 26, 2003

1. Appropriate patients for PHOTOFRIN PDT

   a) The diagnosis of high-grade dysplasia was confirmed by the Central Reference Laboratory in about 50% of patients with that diagnosis. Discuss what impact the inability to confirm a high-grade dysplasia diagnosis has on the use of PHOTOFRIN. Provide recommendations to ensure use of this therapy in the appropriate population.

   b) Should the diagnosis of high-grade dysplasia be confirmed by a reference laboratory of acknowledged experts before PHOTOFRIN PDT is undertaken?

2. Efficacy

   a) Do the applicant's data demonstrate efficacy of PHOTOFRIN PDT in complete ablation of high-grade dysplasia in Barrett's esophagus?

   b) Is a 2-year follow-up period adequate to demonstrate cancer risk reduction in high-grade dysplasia patients treated with PHOTOFRIN PDT?

   c) How frequently should patients who have undergone PHOTOFRIN PDT be monitored by esophagoscopy?

3. Safety:

   Is the safety profile of PHOTOFRIN PDT acceptable?

4. Follow-up

   The applicant is continuing to collect patient follow-up data in the PHO BAR 02 study for an additional 3 years. PHO BAR 01 and PHO BAR 02 taken together will provide a maximum of 5 years of follow-up for patients in the 2 arms of the study. Is this adequate to demonstrate cancer risk reduction in high-grade dysplasia patients?