NDA 20-671/S-004

SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
P.O. Box 5089, Mail Code UP4330
Collegeville, PA 19426-0989

Attention: Richard Swenson, Ph.D.
Associate Director, U.S. Regulatory Affairs

Dear Dr. Swenson:

Please refer to your supplemental new drug application dated December 5, 1997, received December 5, 1997, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hycamtin™ (topotecan hydrochloride) 4 mg for Injection.

We acknowledge receipt of your submissions dated December 23 and 24, 1997; March 19 and 27; April 28 and 30; May 5 and 7; June 26; July 6 and 9; and August 4 and 5, 1998. The user fee goal date for this application is December 5, 1998.

This supplemental new drug application provides for the use of Hycamtin™ in the treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the phase 3 study) or at least 90 days (in the phase 2 studies) after chemotherapy.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-671/S-004." Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Debra Catterson, Project Manager, at (301) 827-1544.

Sincerely,

Robert Temple, M.D.
Director,
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Labeling