DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-671/S012

SmithKline Beecham d/b/a GlaxoSmithKline
Attention: Richard Swenson, Ph.D.
Director, U.S. Regulatory Affairs
2301 Renaissance Boulevard
King of Prussia, PA 19406-2772

Dear Dr. Swenson:

Please refer to your supplemental new drug application dated March 10, 2003, received March 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hycamtin (topotecan hydrochloride) Injection.

This supplemental new drug application provides for the addition of a Geriatric subsection pursuant to the August 27, 1997 final rule.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon enclosed labeling text submitted March 10, 2003.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted March 10, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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-012." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sheila Ryan, Regulatory Project Manager, at (301) 594-5771.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director, Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur

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