DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020981/S-002

SUPPLEMENT APPROVAL

SmithKlineBeecham Corporation d/b/a GlaxoSmithKline
Attention: Thomas F. Kline
US Regulatory Affairs
1250 S. Collegeville Road
Collegeville, PA 19426

Dear Mr. Kline:

Please refer to your Supplemental New Drug Application (sNDA) dated July 29, 2008, received July 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hycamtin® (topotecan hydrochloride) Capsules, 0.25 and 1 mg.

We also acknowledge receipt of your submission dated February 2, 2009.

This "Prior Approval" supplemental new drug application proposes the addition of new safety information regarding the occurrence of interstitial lung disease (ILD) in the Highlights, and Warnings and Precautions section of the prescribing information (PI). Additional text regarding ILD was also placed in the Postmarketing Experience subsection of the Adverse Reactions section of the PI, as well as in the 'possible side effects' section of the Patient Information Leaflet (PIL).

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20981	SUPPL-2	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	HYCAMTIN (TOPOTECAN HCL) CAPS

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

/s/

AMNA IBRAHIM
06/30/2010