DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020671/S-016
NDA 020671/S-017

SUPPLEMENT APPROVAL

GlaxoSmithKline
One Franklin Plaza
200 North 16th Street
Philadelphia, PA 19102

Attention: Thomas F. Kline
Director
Regulatory Affairs

Dear Mr. Kline:

Please refer to your supplemental new drug applications dated September 19, 2007, received September 19, 2007, and June 19, 2009, received June 19, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hycamtin® (topotecan hydrochloride) Injection, 4 mg.

We also acknowledge receipt of your submissions dated February 2, 2009; June 19, 2009; December 7, 2009; January 28, 2010, and February 23, 2010.

The Changes Being Effected supplemental new drug application (S-016) provides for new safety information and revisions to the 'WARNINGS' section, 'Neutropenia' and 'Pregnancy' subsections; the 'PRECAUTIONS' section, 'Nursing Mothers' subsection; and the 'ADVERSE REACTIONS' section, 'Postmarketing Reports of Adverse Reactions' subsection.

The Prior Approval supplemental new drug application (S-017) provides for draft labeling according to the Physician's Labeling Rule (PLR) format, in addition to the aforementioned provisions made in the Changes Being Effected supplement dated September 19, 2007.

We have completed our review of this 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, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert).

For administrative purposes, please designate this submission, "SPL for approved **NDA 020671/S-016 and NDA 020671/S-017".**

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at (301) 847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form.
For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20671	SUPPL-17	GLAXOSMITHKLINE	HYCAMTIN (TOPOTECAN HCL) IV 4MG
NDA-20671	SUPPL-16	GLAXOSMITHKLINE	HYCAMTIN (TOPOTECAN HCL) IV 4MG

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

/s/

ROBERT L JUSTICE
03/26/2010