DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022059/S-003
NDA 022059/S-006

SUPPLEMENT APPROVAL

SmithKline Beecham (Cork) Ltd d/b/a GlaxoSmithKline
Attention: Richard Swenson, Ph.D., Senior Director
GlaxoSmithKline UP4110
1250 S. Collegeville Road, POB 5089
Collegeville, PA 19426-0989

Dear Dr. Swenson:

Please refer to your supplemental new drug applications dated September 12, 2007, received September 12, 2007, and December 5, 2008, received December 5, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tykerb® (lapatinib) Tablets, 250 mg.

We acknowledge receipt of your submissions dated November 3, 2008; February 11, 2009; and January 27(2), 2010.

Please also refer to our accelerated approval letter dated January 29, 2010, for supplement (S-007).

Prior approval supplement (S-003), provided for the removal of the QT interval data from the WARNINGS and PRECAUTIONS section and to revise the information as it appears in the CLINICAL PHARMACOLOGY-QT PROLONGATION section of the approved labeling.

Prior approval supplement (S-006) provided for the addition of hypersensitivity to the CONTRAINDICATIONS and ADVERSE REACTIONS sections and nail disorders to the ADVERSE REACTIONS section of the Tykerb® full prescribing information and patient information leaflet.

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 and with the minor editorial revisions listed below/indicated in the enclosed labeling.

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)] 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. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 022059/S-003 and S-006.**"

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}

Ann T. Farrell, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure (label)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22059	SUPPL-6	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	TYKERB TABLETS
NDA-22059	SUPPL-3	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	TYKERB TABLETS

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

/s/

ANN T FARRELL
01/29/2010