DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-059/S-004

SmithKlineBeecham Corporation d/b/a GlaxoSmithKline
2301 Renaissance Blvd., Building 510
P.O. Box 61540
King of Prussia, PA 19406-2772

Attention: Richard Swenson, Ph.D.
Senior Director, US Regulatory Affairs

Dear Dr. Swenson:

Please refer to your supplemental new drug application dated March 7, 2008 received March 7, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TYKERB® (lapatinib) tablets, 250 mg.

We also acknowledge receipt of your submissions dated May 22 and June 4, 2008, received May 22 and June 4, 2008.

This supplemental new drug application provides for the inclusion of language pertaining to hepatotoxicity in a boxed warning and in the WARNINGS and PRECAUTIONS, ADVERSE REACTIONS, and FDA-approved patient labeling sections of the approved TYKERB® labeling.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-059/S-004**." Approval of this submission by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling text/submitted labeling dated August 9, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

We request that you submit a copy of the letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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.
Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure-Label

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

/s/

Robert Justice
7/7/2008 01:57:50 PM