DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-059/S-001

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 22, 2007, received March 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TYKERB® (lapatinib) tablets, 250 mg.

This "Changes Being Effected" supplemental new drug application proposes corrections of typographic errors in the original label that provided for TYKERB® in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors over-express HER2 (ErbB2) and who have received prior therapy including an anthracycline, a taxane and trastuzumab.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

We note that your final printed labeling (FPL) dated March 22, 2007, received March 22, 2007 will be retained in your file as it is superseded by your supplement NDA 22-059/S-001.

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.
Division Director
Division of Drug Oncology Products
Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

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

4/27/2007 04:23:33 PM