DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022465/S-011/PMR 1549-3

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

GlaxoSmithKline
Attention: Thomas Kline
Director, Regulatory Affairs
1250 S. Collegeville Road UP4110
Collegeville, PA 19426

Dear Mr. Kline:

Please refer to your Supplemental New Drug Application (sNDA) dated March 16, 2011, received March 16, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Votrient®, (pazopanib) Tablet 200 mg and 400 mg.

We also refer to your October 4, 2011, submission containing the final report for PMR 1549-3 (hepatic impairment trial, protocol NCI 8063).

We acknowledge receipt of your amendments dated October 24, November 9, December 22, 2011; January 24, February 9, 23, and March 1, 2012.

This Prior Approval supplemental new drug application provides for 1) updated language regarding dose adjustment in patients with hepatic impairment and 2) new information regarding the potential for drug interactions with simvastatin. Specific sections of the prescribing information affected by this supplement are Highlights-Recent Major Changes, changes in Sections 2.2 and 5.1; Highlights-Drug Interactions, addition of simvastatin information; Section 2.2-Dose Modification Guidelines, hepatic impairment guideline added; Section 5.1-Warnings and Precautions-Hepatic Effects, language added regarding simvastatin caution and hepatic impairment dose adjustments; Section 7.3-Drug Interactions-Effect of Concomitant use of Votrient and Simvastatin (new information added); Section 8.6-Hepatic Impairment (updated language); Section 12.3-Pharmacokinetics (updated language); and Medication Guide, addition of simvastatin information.

We have completed our review of this supplemental application. 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and patient package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated and received October 4, 2011, containing the final report for the following postmarketing requirement listed in the October 19, 2009, approval letter.

PMR 1549-3 Submit the final report of the hepatic impairment trial, protocol NCI 8063.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the October 19, 2009, approval letter that are still open.

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 Amy Tilley, Regulatory Project Manager, at (301) 796-3994.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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
03/20/2012
For Dr Justice