DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022465/S-010/S-012/PMR 1549-5

SUPPLEMENT APPROVALS
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 June 28, 2011, received June 28, 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 acknowledge receipt of your amendments dated July 6, 18 and 27, August 4, September 9, 19 and 28, October 7, 10, 13, 19, 21, 26 and 28, November 2, 9 11, 16, and 17, 2011; January 17 and 27, February 9, 17, 20 and 24, March 26, April 5, 12, 23 and 24, 2012.

This "Prior Approval" efficacy supplemental new drug application (S-010) provides for the following indication.

"Votrient is indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. Limitation of Use: The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated."

We also refer to your December 14, 2011, "Prior Approval" labeling supplemental new drug application (S-012) which provides for changes to HIGHLIGHTS OF PRESCRIBING INFORMATION, INDICATIONS AND USAGE, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, PATIENT COUNSELING INFORMATION, and the Medication Guide.

We acknowledge receipt of your amendments dated March 13 and 26, April 5, 12 and 23, 2012.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 Medication Guide, 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in 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 address above or by fax to 301-847-8444.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated and received September 15, 2011, containing the final report for the following postmarketing requirement listed in the October 19, 2009, approval letter.

PMR 1549-5 To adequately determine the influence of strong CYP3A4 inhibitors on the exposure of pazopanib following oral clinical pazopanib doses, conduct a drug-drug interaction trial in patients using clinical doses of oral pazopanib and a strong CYP3A4 inhibitor (e.g., ketoconazole). The protocol should be submitted prior to initiation for review and concurrence.

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

ENCLOSURES:
Content of Labeling
Medication Guide

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
04/26/2012