DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022465/S-002 **SUPPLEMENT APPROVAL**

GlaxoSmithKline
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

Attention: Ellen S. Cutler
Senior Director, US Regulatory Affairs
Oncology

Dear Ms. Cutler:

Please refer to your supplemental new drug application dated October 27, 2009, received October 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Votrient™ (pazopanib hydrochloride) tablets, 200 mg and 400 mg.

We also acknowledge receipt of your amendment also dated October 27, 2009, and your REMS assessment dated November 25, 2009.

This Prior Approval supplemental new drug application provides for a proposed modification to the approved Risk Evaluation and Mitigation Strategy (REMS). This supplement also provides for the removal of the following 200 mg presentations from the full prescribing information:

• Bottles of 30 tablets: NDC 0173-0804-13
• Bottles of 90 tablets: NDC 0173-0804-59

Further, the supplement provides for revisions to the text on the container label referring to the Medication Guide per the October 19, 2009 REMS to state: "Dispense the Medication Guide, attached or provided separately, to each patient pursuant to Federal Law."

In addition, the supplement provides for the removal of the 400 mg strength tablet from the prescribing information (Dosage Forms and Strengths, Description, How Supplied/Storage and Handling), including the Highlights section (Dosage Forms and Strengths) of the labeling and the Medication Guide (What are the Ingredients in Votrient?).

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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Votrient™ (pazopanib hydrochloride) tablets was originally approved on October 19, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. The proposed modified REMS includes a revised Medication Guide reflecting the removal the 400 mg strength tablet.

Your proposed modified REMS, submitted on October 27, 2009, and appended to this letter, is approved. The REMS assessment plan will remain the same as that approved on October 19, 2009.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022465 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022465
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022465
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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 agreed-upon labeling text. 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 022465/S-002**."

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels (submitted May 15, 2009) as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved **NDA 022465/S-002**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

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, at least 24 hours prior to issuing this letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, 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 me, Kim J. Robertson, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

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

Enclosure(s)
Labeling, REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22465	SUPPL-2	GLAXOSMITHKLINE	VOTRIENT TABLETS

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
04/27/2010