DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022465/S-003
NDA 022465/S-005

SUPPLEMENT APPROVAL

Glaxo Wellcome Manufacturing Pte Ltd d/b/a GlaxoSmithKline
Attention: Thomas F. Kline
Director, Regulatory Affairs, Oncology
1250 South Collegeville Road
Collegeville, PA 10426

Dear Mr. Kline:

Please refer to your Supplemental New Drug Applications (sNDA) dated February 22, 2010, received February 22, 2010, and August 5, 2010, received August 5, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Votrient (pazopanib hydrochloride) 200 mg and 400 mg tablets.

We acknowledge receipt of your amendments dated September 2, 2010; April 18, 2011 (2) and July 11, 2011 (2).

The "Changes Being Effected" (CBE) supplemental new drug application (S-003) provides for revisions to the Full Prescribing Information; Adverse Reactions, Clinical Trials Experience and Cardiac Dysfunction Section of the Package Insert for Votrient (pazopanib hydrochloride) 200 mg and 400 mg tablets.

The "Prior Approval" supplemental new drug application (S-005) provides for revisions regarding hypertension to the Highlights of Prescribing Information, Recent Major Changes, and Warnings and Precautions; Full Prescribing Information, Warnings and Precautions, Adverse Reactions - Clinical Trials Experience and Clinical Pharmacology - Mechanism of Action Sections of the Package Insert for Votrient (pazopanib hydrochloride) 200 mg and 400 mg tablets and to the Medication Guide, and a proposed modification to the approved risk evaluation and mitigation strategy (REMS).

The REMS for Votrient(pazopanib hydrochloride) tablets was originally approved on October 19, 2009. The REMS consisted of a Medication Guide and a timetable for submission of assessments of the REMS. You submitted a request for FDA to release the REMS requirement on March 14, 2011. Because we approved your request to release the REMS requirement on April 21, 2011, the proposed REMS modification included in S-005 is no longer applicable. Therefore, we consider S-005 to provide only for the labeling changes described above.

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.

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, 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 none of these criteria apply to your applications, 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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Jamila Mwidau, Regulatory Project Manager, at (301) 796-4989.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy 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
10/21/2011