DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022465/S-013

SUPPLEMENT APPROVAL

Glaxo Wellcome Manufacturing Pte Ltd d/b/a GlaxoSmithKline
Attention: Thomas F. Kline
Director Global Regulatory Affairs
1250 South Collegeville Road
Collegeville, PA 19426

Dear Mr. Kline:

Please refer to your Supplemental New Drug Application (sNDA) dated May 17, 2012 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Votrient® (pazopanib), 200 mg and 400 mg Tablets.

We acknowledge receipt of your amendment(s) dated August 14, October 2, and October 18, 2012.

This Prior Approval labeling supplemental new drug application provides the changes to

1. Highlights - Recent Major Changes
2. Highlights - addition to animal toxicity
3. Warnings and Precautions - section 5.15 - addition of juvenile animal toxicity
4. Use in Specific Population - section 8.4 – addition of juvenile animal toxicity

We have completed our review of this supplemental application, as amended. 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), 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).

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314,8 and 314.81).

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products I
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
US Food and Drug Administration

ENCLOSURE(S):
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
11/15/2012