DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022465/S-006

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

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

Dear Mr. Kline:

Please refer to your Supplemental New Drug Application (sNDA) dated March 14, 2011, received March 14, 2011, 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 risk evaluation and mitigation strategy (REMS) assessment by referring to the relevant information in your annual report dated December 17, 2010.

This prior approval supplemental application provides for a proposed REMS modification requesting the elimination of the approved REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Votrient™ (pazopanib hydrochloride) Tablets was originally approved on October 19, 2009, and the most recent REMS modification was approved on April 27, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Votrient™ (pazopanib hydrochloride) Tablets.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Votrient™ (pazopanib hydrochloride) Tablets outweigh its risks. Therefore, we agree with your proposal and a REMS for Votrient™ (pazopanib hydrochloride) Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Susan Jenney, Regulatory Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Office Director
Office of Oncology Drug Products
Center of Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RICHARD PAZDUR
04/21/2011