DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022291/S-003 **SUPPLEMENT APPROVAL**

Smith Kline Beecham Corporation
d/b/a/GlaxoSmithKline
Attention: Dennis R. Williams, R.Ph.
Associate Director, Regulatory Affairs, Oncology
1250 South Collegeville Rd, UP4110
Collegeville, PA 19426

Dear Mr. Williams:

Please refer to your supplemental new drug application dated June 10, 2009, received June 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Promacta® (eltrombopag) Tablets.

We acknowledge receipt of your submissions dated September 16 and 30, October 23, November 30, 2009 and January 5 and 28, and February 25, 2010, and a Risk Evaluation and Mitigation Strategy (REMS) assessment dated November 30, 2009.

The REMS for Promacta® (eltrombopag) Tablets was originally approved on November 20, 2008. This supplemental new drug application provides for proposed modifications to the approved REMS and includes the following revisions:

- Revise the Medication Guide and Medication Guide attachment to the Overview for Patients (Patient Brochure) to add information about blood clots.
- Add the 75 mg tablet that was approved on September 8, 2009 to the:
  - Pharmacy Inventory Tracking log
  - Medication Guide attachment to the Overview for Patients (Patient Brochure)
- Add information to facilitate inventory reconciliation and to add the 75 mg tablet that was approved on September 8, 2009 to the:
  - Pharmacy Inventory Tracking Log
- Include “in-patient” or “outpatient” identifiers to the:
  - VA Pharmacy Authorization Form
  - Hospital Pharmacy Form
- Add e-mail to the methods of delivery a pharmacy can use to send the Inventory Tracking Log monthly to PROMACTA CARES to the:
  - Controlled Distribution Procedure
- Separate the Hospital Pharmacy/Dispensing Clinic Authorization Form into two separate forms; one specific for hospitals and one specific for dispensing clinics, to address the

issue of determining the pharmacy type on the form which causes them to be completed manually to the:
    - Hospital Pharmacy Authorization Form
    - Dispensing Clinic Authorization Form
- Delete the Dear Managed Care, Wholesaler, Distributor and Specialty Pharmacy Customer Introduction Letter (Dear Customer Letter) from the elements to assure safe use since the distribution of these letters has been completed.

We have completed our review of this supplemental application, as amended. Your proposed modified REMS, submitted on June 10, 2009, amended February 25, 2010, and appended to this letter, is approved. The REMS consists of the Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. The timetable for submission of assessments will remain the same as that approved on November 20, 2008 with the original approval of Promacta (eltrombopag).

There are no changes to the REMS assessment plan.

We remind you that the requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(A), an assessment of the extent to which the elements to assure safe use are meeting the goal or goals to mitigate a specific serious risk listed in the labeling of the drug, or whether the goal or goals or such elements should be modified.

The requirements for assessments of an approved REMS also include, under section 505-1(g)(3)(B) and (C), requirements for information on the status of any post-approval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessment provisions in 505-1(g) could result in enforcement action.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in Section 505-1(g)(2)(A) of FDCA.

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

NDA 022291 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022291
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022291
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

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

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 Diane Leaman, Safety Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Ira Krefting, M.D.,
Deputy Director for Safety
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Modified REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22291	SUPPL-3	GLAXOSMITHKLINE	PROMACTA

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

/s/

IRA P KREFTING
03/05/2010