DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022291/S-011

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

GlaxoSmithKline, LLC
Attention: Dennis Williams, Pharm.D
Director, Global Regulatory Affairs, Oncology
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426

Dear Dr. Williams:

Please refer to your Supplemental New Drug Application (sNDA) dated September 11, 2013 received September 11, 2013 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Promacta® (eltrombopag).

We acknowledge receipt of your amendments dated March 3 and 26, 2014 and April 1, 2014.

This "Prior Approval" supplemental new drug application provides for changes to the Section 12.3 (Pharmacokinetics) of the Prescribing Information, describing the effect of telaprevir on eltrombopag PK and the effect of eltrombopag on telaprevir PK in healthy adult subjects.

APPROVAL & LABELING

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.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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 that includes labeling changes 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).

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submissions dated August 30, September 11, 2013; January 8 and January 23, 2014, containing the final reports for the following postmarketing commitment listed in the November 16, 2012 approval letter.

PMC 1969-1 Conduct a PK trial to evaluate the effect of boceprevir and telaprevir on eltrombopag PK and the effect of eltrombopag on boceprevir and telaprevir PK in healthy adult subjects.

The timetable you submitted on November 8, 2012 states that you will conduct this trial according to the following schedule:

Final Protocol Submission:	07/2012
Trial completion:	02/2013
Final Report submission:	08/2013

We have reviewed your submissions and conclude that the above commitment was fulfilled.

We remind you that there are postmarketing requirements listed in the November 20, 2008 approval letter and a postmarketing requirement listed in the June 23, 2009 postapproval postmarketing requirement letter that are still open.

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 Mara Miller, Regulatory Project Manager, at (301) 796-0683.

Sincerely,

{See appended electronic signature page}

Robert C. Kane, MD
Deputy Director for Safety
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

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/

ROBERT C KANE
04/10/2014