DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22291/S-013

SUPPLEMENT APPROVAL
RELEASE REMS 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 April 23, 2014, received April 23, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Promacta® (eltrombopag) Tablets, 12.5 25, 50 and 75 mg.

This supplemental new drug application proposes to eliminate the requirement for the approved Promacta® (eltrombopag) Tablets Risk Evaluation and Mitigation Strategy (REMS.

APPROVAL

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

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 application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Promacta® (eltrombopag) Tablets was originally approved on November 20, 2008, and the most recent REMS modification was approved on December 6. 2011. The REMS consists of a communication plan, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Promacta® (eltrombopag) Tablets.

The most recent REMS assessment, dated June 30, 2012, demonstrated that the communication plan has been completed. Additionally, there is cumulative evidence to suggest that the original safety concerns addressed by the REMS were not, in fact, occurring at a frequency or degree of severity that was originally anticipated; hence, labeling has been revised, to re-characterize these risks.

Because the benefit-risk profile has improved since the time of REMS approval, we have determined that it is no longer necessary to include the communication plan as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS for Promacta® (eltrombopag) Tablets is no longer required.

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

Sincerely,

{See appended electronic signature page}

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

ROBERT C KANE
07/16/2014