



NDA 202155/S-014

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Bristol-Myers Squibb Company
Attention: Diptee Gajjar, B. Pharm., Ph.D.
Director, Global Regulatory Lead, Global Regulatory & Safety Sciences
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Gajjar:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 9, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Eliquis (apixaban) 2.5 mg and 5 mg Tablets.

We also refer to our REMS Modification Notification letter dated January 26, 2016, and we acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated June 26, 2014.

This prior approval supplemental new drug application provides for proposed modification to the approved REMS to eliminate the requirement for the approved REMS for Eliquis (apixaban).

APPROVAL & LABELING

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Eliquis (apixaban) was originally approved on December 28, 2012, and the most recent modification was approved on August 12, 2014. The REMS consists of a communication plan, and a timetable for submission of assessments of the REMS.

In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modifications:

- Removal of the Communication Plan as an element of the REMS
- Elimination of the required Eliquis (apixaban) REMS

As communicated in the January 26, 2016, REMS Modification Notification Letter, we determined a communication plan is no longer necessary to include as an element of the approved REMS because the communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goals.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Eliquis (apixaban).

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, please call:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

MARY R SOUTHWORTH
03/02/2016