



NDA 202439/S-012

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Janssen Pharmaceuticals, Inc.
Attention: Lori Birkenberger, Ph.D.
Director
920 Highway 202 South
P.O. Box 300
Raritan, NJ 08869

Dear Dr. Birkenberger:

Please refer to your Supplemental New Drug Application (sNDA) dated January 20, 2014, received January 22, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xarelto (Rivaroxaban) 15 mg and 20 mg Tablets.

We also refer to our REMS Modification Notification letter dated January 10, 2014, and we acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 25, 2013.

This supplemental new drug application proposes to eliminate the requirement for the approved Xarelto (Rivaroxaban) REMS.

APPROVAL

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 Xarelto (Rivaroxaban) was originally approved on November 4, 2011, and the most recent REMS modification was approved on August 7, 2013. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

Because the communication plan has been completed and the most recent assessment demonstrated that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, a REMS for Xarelto 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, 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
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
02/12/2014