DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22406/S-010

SUPPLEMENT APPROVAL

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

Dear Ms. Birkenberger:

Please refer to your Supplemental New Drug Application (sNDA) dated February 4, 2014, received February 4, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xarelto® (rivaroxaban) Tablets.

This "Prior Approval" supplemental new drug application provides for revisions to the **DRUG INTERACTIONS** and **CLINICAL PHARMACOLOGY** sections of the Xarelto (rivaroxaban) tablets package insert to include study results from the final study report entitled "An Open-Label Study to Estimate the Effect of Multiple Doses of Erythromycin on the Pharmacokinetics, Pharmacodynamics and Safety of a Single Dose of Rivaroxaban in Subjects with Renal Impairment and Normal Renal Function."

APPROVAL & LABELING

We have completed our review of this supplemental application. 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

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).

PREA

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.

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

We have received your submission dated June 28, 2012, containing the final report for the following postmarketing requirement listed in the July 1, 2011 approval letter.

PMR 1797-2 Perform a clinical trial to evaluate the effect of renal impairment (i.e., mild, moderate, severe) plus the concurrent use of P-gp and moderate inhibitors of CYP3A4 on the pharmacokinetics, pharmacodynamics, and safety of rivaroxaban in volunteers so that appropriate dosing recommendations can be developed in these populations. Final Protocol submission: submitted 2/4/2011; Study Trial Completion Due: 2/29/2012; Final Report Submission Due: 6/30/2012.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there is a postmarketing requirement and a postmarketing commitment listed in the July 1, 2011 approval 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 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 Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
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
02/13/2014