ANDA 208334

**ANDA APPROVAL**

Micro Labs USA, Inc.
U.S. Agent for Micro Labs Limited
Attention: Umesh K. Jayakumar
Associate Vice President

Dear Umesh K. Jayakumar:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 1, 2015, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xarelto Tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen) NDA - 022406.

The RLD upon which you have based your ANDA, Janssen's Xarelto Tablets, 10 mg, 15 mg and 20 mg, is subject to a period of patent protection. The following patent and expiration date (with pediatric exclusivity added) is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

| U.S. Patent Number | Expiration Date |
|---|---|
| 9,539,218 (the '218 patent) | August 17, 2034 |

Your ANDA contains a paragraph IV certification to the '218 patent, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Rivaroxaban Tablets USP, 10 mg, 15 mg and 20 mg, under this ANDA. You have notified the Agency that Micro Labs Limited (Micro) complied with the requirements of section 505(j)(2)(B) of the FD&C Act.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

## COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

## REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

*{See appended electronic signature page}*

For Kendra S. Stewart, R.Ph., Pharm.D.
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Catherine Poole

Digitally signed by Catherine Poole
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