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July 14, 2020

**VIA REGULATIONS.GOV**
**Docket No. FDA-2019-P-3022**

Dockets Management
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Re: Amendment to an ANDA Suitability Petition
Revision to Draft Labeling to Support the Submission of an ANDA
for Rivaroxaban Capsules, 2.5 mg, 10 mg, 15 mg and 20 mg.

Dear FDA Staff:

Reference is made to the ANDA suitability petition FDA-2019-P-3022, received on June 24, 2019, seeking permission to file an ANDA for Rivaroxaban Capsules, 2.5 mg, 10 mg, 15 mg and 20 mg.

We acknowledge receipt of the following comment from FDA:

1. We note that your claim in the petition of a dosage form change is inconsistent with typical capsule administration instructions (i.e., crush the capsule). Please clarify and/or submit a revised proposed package insert.

Attached hereto is a copy of a revised draft package insert addressing FDA's comment. Please note that we have left information in the package insert in Section 12.3 regarding the **"crushed tablet"** because it refers to a clinical study on the RLD, and is also so indicated.

Please let me know if you have any further questions or if you need any additional information.

Sincerely yours,

David L. Rosen, BS Pharm., JD

Attachment
Cc: ANDAFiling@fda.hhs.gov
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