DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 24, 2019

David L. Rosen
Foley & Lardner, LLP
3000 K St., N.W., Suite 600
Washington, DC 20007

Sent via email to: drosen@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to declare that:

1. Rivaroxaban Capsules, 2.5 mg, 10 mg, 15 mg, 20 mg are suitable for submission as an Abbreviated New Drug Application (ANDA), pursuant to 21 CFR §314.94; and

2. The reference product on which the contents of this petition are based is XARELTO (rivaroxaban) Tablets 2.5 mg, 10 mg, 15 mg and 20 mg.

Your submission was received by this office on 06/24/2019. It was assigned docket number FDA-2019-P-3022. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.06.25 12:52:41 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)