DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 21, 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 that an ANDA may be submitted for pantoprazole sodium for delayed-release oral suspension containing 20 mg and 40 mg pantoprazole as enteric granules packaged in a unit dose capsule supplied in a bottle of 30 capsules instead of in a unit dose packet supplied in a unit dose carton of 30 packets was received by this office on 11/21/2019.

It was assigned docket number FDA-2019-P-5535. 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: 2019.11.22 13:43:06 -05'00'

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