DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 3, 2019

David L. Rosen, BS Pharm, JD
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 determine that an Abbreviated New Drug Application (ANDA) may be submitted for a drug product that is not identical to the Reference Listed Drug (RLD) for esomeprazole magnesium delayed-release capsules was received by this office on 12/03/2019.

It was assigned docket number FDA-2019-P-5691. 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: 2019.12.04 13:38:27 -05'00'

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