DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 26, 2020

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to designate NDA 203629 (Neostigmine Methylsulfate Injection Solution) as both an RLD and a RS for purposes of FDA evaluation of Abbreviated New Drug Applications ("ANDAs") for Neostigmine Methylsulfate Injection Solution was received by this office on 02/26/2020.

It has been assigned docket number FDA-2020-P-0947. 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,

Karen Malvin
Digitally signed by Karen Malvin
Date: 2020.02.27 09:20:46 -05'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)