DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 5, 2019

John A. Sowards
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Sent via email to: JSowards@nexsenpruet.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA designates Neostigmine Methylsulfate Injection,Solution 3 mg/3 mL (1 mg/mL), NDA No. 203629, as RLD for the purposes of submitting an ANDA for a generic version of this drug product was received by this office on 04/04/2019.

It was assigned docket number FDA-2019-P-1636. 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: 2019.04.05 13:21:38 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)