FDA U.S. FOOD & DRUG ADMINISTRATION

John A. Sowards
Nexsen Pruet, LLC
P.O. Box 2426
Columbia, SC 29202

Re: Docket No. FDA-2019-P-1636

SEP 27 2019

Dear Mr. Sowards:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 4, 2019, and submitted on behalf of Fresenuis Kabi USA, LLC. Your petition requests that the Agency designate Neostigmine Methylsulfate solution, 3 mg/3 mL, NDA 203629, as a reference listed drug.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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