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

September 18, 2020

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

Dear John Sowards:

This letter responds to your citizen petition received on April 4, 2019 (Petition), requesting that the Food and Drug Administration (FDA or Agency) designate neostigmine methylsulfate solution, 3 mg/3 mL, approved under new drug application (NDA) 203629 held by Fresenius Kabi USA, LLC (Fresenius Kabi) as an additional reference listed drug (RLD) in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[1]

Since the time the Petition was submitted, FDA has updated the Orange Book to designate neostigmine methylsulfate, 3 mg/3 mL, approved under NDA 203629 held by Fresenius Kabi, as an RLD. Therefore, we dismiss the Petition as moot.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
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Date: 2020.09.15 16:12:01 -04'00'

Patrizia Cavazzoni, M.D.
Acting Director
Center for Drug Evaluation and Research