Kurt Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005

September 18, 2020

Re: Docket No. FDA-2020-P-0947

Dear Kurt Karst:

This letter responds to your citizen petition received on February 26, 2020 (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) and select neostigmine methylsulfate solution, 3 mg/3 mL, approved under NDA 203629 held by Fresenius Kabi as a Reference Standard (RS) 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 and select neostigmine methylsulfate, 3 mg/3 mL, approved under NDA 203629 held by Fresenius Kabi, as a RS. Therefore, we dismiss the Petition as moot.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300121270, cn=Douglas C. Throckmorton -S
Date: 2020.09.18 13:51:38 -04'00'

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

[1] The Orange Book is available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.