U.S. FOOD & DRUG ADMINISTRATION

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

August 21, 2020

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

Dear Mr. Karst:

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 February 26, 2020. Your petition requests that the Agency designate Neostigmine Methylsulfate solution, 3 mg/3 mL, NDA 203629, as a reference listed drug and reference standard.

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 Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.08.21 09:11:23 -04'00'

Carol J. Bennett
Deputy Director
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Center for Drug Evaluation and Research

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