Molly Ventrelli
Sr. VP Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

August 29, 2022

Re: Docket No. FDA-2022-P-0287

Dear Ms. Ventrelli:

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 March 3, 2022. Your petition requests that the Agency assign a therapeutic equivalence code to neostigmine methylsulfate intravenous solution, 0.5 milligrams (mg)/milliliter (mL) and 1 mg/mL, approved under new drug application 203629.

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
Date: 2022.08.29 13:39:46 -04'00'

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993