March 4, 2022

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

Sent via email to: Molly.Ventrelli@fresenius-kabi.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug designate Neostigmine Injection, 0.5 and 1.0 mg/mL, manufactured by FK USA (NDA 203692), as a therapeutic equivalent, with an 'AB' rating, to the reference listed drug (RLD) Bloxiverz®, NDA 204078, by Avadel Legacy Pharmaceuticals LLC was received and processed under CFR 10.30 by this office on 03/03/2022.

It was assigned docket number FDA-2022-P-0287. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.04 14:51:42 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)