July 22, 2022

Marcela Ruvalcaba
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Sent via email to: marcela.ruvalcaba@fresenius-kabi.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug designate Glycopyrrolate Injection, 0.6 mg per 3 mL pre-filled syromge, manufactured by FK USA (NDA 214919), as a therapeutic equivalent with an 'AP' rating, to the reference listed drug, Robinul®, NDA 017558, by Hikma Pharmaceuticals International Ltd was received and processed under CFR 10.30 by this office on 07/22/2022.

It was assigned docket number FDA-2022-P-1656. 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,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.07.22 16:50:20 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)