DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 21, 2020

Mitul Chatterjee
Head, Regulatory Affairs
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield, IL 60015

Sent via email to: mitul_chatterjee@baxter.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether QUELICIN PRESERVATIVE FREE (Succinylcholine Chloride Injection USP, 20 mg/mL), approved under New Drug Application ("NDA") number 008845, held by HOSPIRA INC, has been voluntarily withdrawn for reasons of safety or effectiveness was received by this office on 12/21/2020.

It was assigned docket number FDA-2020-P-2317. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.12.22 14:43:38 -05'00'

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