DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 2, 2022

Mitul Chatterjee
Director, Regulatory Affairs
Baxter Healthcare Corporation
2 Esterbrook Lane
Cherry Hill, NJ 08003

Sent via email to: mitul_chatterjee@baxter.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug Administration determine whether REGLAN (metoclopramide injection, USP), 5 mg/mL, approved under New Drug Application (NDA) number 017862, held by HIKMA PHARMACEUTICALS USA INC, has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 02/02/2022.

It was assigned docket number FDA-2022-P-0115. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that 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: 2022.02.02 16:14:38 -05'00'

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