November 14, 2022

Rajesh Gurjar, Senior Manager, Regulatory Affairs
Baxter Healthcare Corporation

Sent via email to: rajesh_gurjar@baxter.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether D.H.E 45 (dihydrpergotamine mesylate) injection, USP 1 mg/mL, approved under New Drug Application ("NDA") 005929, held by BAUSH HEALTH US LLC, has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 11/11/2022.

It was assigned docket number FDA-2022-P-2842. 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: 2022.11.14 09:35:34 -05'00'

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