May 27, 2022

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 2005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether Sinemet CR (carbidopa/levodopa) Tablets, 50 mg/200mg and 25 mg/100 mg, approved under New Drug Application number 019856, held by Organon, LLC has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 05/27/2022.

It was assigned docket number FDA-2022-P-0948. 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: 2022.05.27 14:27:24 -04'00'

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