August 18, 2022

Kurt Karst
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005

Sent via email to: Kkarst@hpm.com

Dear Petitioner:

Your submission requesting that the FDA determine whether TOPAMAX (topiramate capsules) Sprinkle Capsules, 50 mg, approved under New Drug Application ("NDA") number 020844, held by Janssen Pharmaceuticals, Inc., has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 08/17/2022.

It was assigned docket number FDA-2022-P-1939. 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: 2022.08.18 12:12:46 -04'00'

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