U.S. FOOD & DRUG ADMINISTRATION

Kurt Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005

February 21,2023

Re: Docket No. FDA-2022-P-1939

Dear Mr. Karst:

This letter responds to your citizen petition received on August 17, 2022, requesting that the Food and Drug Administration (FDA) determine whether Topamax (topiramate) sprinkle capsules, 50 milligrams (mg), approved under new drug application (NDA) number 020844, held by Janssen Pharmaceuticals, Inc., was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Topamax (topiramate) sprinkle capsules, 50 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Topamax (topiramate) sprinkle capsules, 50 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-4078.

Sincerely,

Alexandria S. Fujisaki -S

Digitally signed by Alexandria S. Fujisaki -S
Date: 2023.02.21 10:14:21 -05'00'

Alexandria Fujisaki
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure