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

March 7, 2023

Re: Docket No. FDA-2022-P-3125

Dear Mr. Karst:

This letter responds to your citizen petition received on December 6, 2022, requesting that the Food and Drug Administration (FDA) determine whether lithium citrate oral solution, 8 milliequivalents (mEq)/5 milliliters (mL), approved under new drug application (NDA) 018421 and held by Hikma Pharmaceuticals, USA Inc., has been withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that lithium citrate oral solution, 8 mEq/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain lithium citrate oral solution, 8 mEq/5 mL, 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) 402-4318.

Sincerely,

Caitlin G. Callahan -S
Digitally signed by Caitlin G. Callahan -S
Date: 2023.03.07 10:18:43 -05'00'

Caitlin Callahan
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure