Mitul Chatterjee
Director, Regulatory Affairs
Baxter Healthcare Corporation
2 Easterbrook Lane
Cherry Hill, NJ 08003

Sent via email to: Mitul_chatterjee@baxter.com

July 13, 2022

Re: Docket No. FDA-2022-P-0115

Dear Ms. Chatterjee:

This letter responds to your citizen petition received on February 2, 2022, requesting that the Food and Drug Administration (FDA) determine whether Reglan (metoclopramide injection, USP), 5 milligrams (mg)/milliliter (mL), approved under new drug application 017862, held by Hikma Pharmaceuticals USA Inc., has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Reglan Injection (metoclopramide injection, USP), Equivalent to (EQ) 5 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Reglan Injection (metoclopramide injection, USP), EQ 5 mg base/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 (301) 796-6650.

Sincerely,

Daniel G. Gottlieb -S

Digitally signed by Daniel G. Gottlieb -S
Date: 2022.07.13 12:34:32 -04'00'

Daniel Gottlieb
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure