U.S. FOOD & DRUG ADMINISTRATION

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005

August 28, 2024

Re: Docket No. FDA-2024-P-0805

Dear Mr. Karst:

This letter responds to your citizen petition received on February 13, 2024, requesting that the Food and Drug Administration (FDA) determine whether Fentanyl Citrate Injection, equivalent to (EQ) 2.5 milligram (mg) base/50 milliliter (mL) (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), approved under the new drug application 215870, held by Exela Pharma Sciences, LLC, were withdrawn for safety or effectiveness reasons.

FDA has reviewed its records and determined that Fentanyl Citrate Injection, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL) were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Fentanyl Citrate Injection, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 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 (240) 402-9917

Sincerely,

Swati V. Rawani -S

Digitally signed by Swati V. Rawani -S
Date: 2024.08.28 09:42:00 -04'00'

Swati Rawani
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure