LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
KURT R. KARST WASHINGTON, D.C. 20005-5929 Direct Dial (202) 737-7544
(202) 737-5600 Kkarst@hpm.com
FACSIMILE
(202) 737-9329
www.hpm.com

February 13, 2024

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

Hyman, Phelps & McNamara, P.C. submits this Petition in accordance with 21 C.F.R. §§ 10.25 and 10.30, and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for safety or effectiveness reasons.

A. ACTIONS REQUESTED

Petitioner requests that FDA determine whether 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), approved under New Drug Application ("NDA") number 215870, held by Exela Pharma Sciences, LLC, has been voluntarily withdrawn for reasons of safety or effectiveness.

B. STATEMENT OF GROUNDS

Under the FDC Act, an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). *See* FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. *See* 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). *See id.* § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and

effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book currently identifies 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), approved on February 8, 2023 under NDA 215870, in the "Discontinued Drug Product List" section. FDA appears to have moved NDA 011795 to the "Discontinued Drug Product List" in the May 2023 Cumulative Supplement to the Orange Book.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of 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), approved under NDA 215870 was due only to commercial considerations. Therefore, Petitioner requests that FDA determine 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), approved under NDA 215870, was not withdrawn for reasons of safety or effectiveness.

C. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

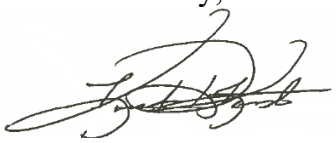
D. ECONOMIC IMPACT STATEMENT

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Sincerely,



Kurt R. Karst