

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

KURT R. KARST

700 THIRTEENTH STREET, N.W.

SUITE 1200

WASHINGTON, D.C. 20005-5929

(202) 737-5600

FACSIMILE

(202) 737-9329

www.hpm.com

Direct Dial (202) 737-7544
kkarst@hpm.com

March 2, 2021

BY 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

RE: Docket No. FDA-2019-P-1678; Withdrawal

Dear Sir or Madam:

The undersigned, on behalf of Petitioner, Exela Pharma Sciences, LLC, hereby withdraws the Citizen Petition, dated April 5, 2019, requesting that FDA assign a Therapeutic Equivalence Evaluation Code for the company's GLYRX-PF (glycopyrrolate injection), 0.2 mg/mL and 0.4 mg/2 mL, approved under New Drug Application 210997.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kurt R. Karst', with a large, stylized flourish at the end.

Kurt R. Karst

KRK/eam