FDA U.S. FOOD & DRUG ADMINISTRATION

SEP 2 7 2019

Aruna Koganti, Ph.D., MBA
Vice President, Regulatory Affairs and Clinical Programs
Exela Pharma Sciences, LLC
P.O. Box 818
1245 Blowing Rock Blvd.
Lenoir, NC 28645

Re: Docket No. FDA-2019-P-1678

Dear Dr. Koganti:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 5, 2019. Your petition requests that the Agency assign a therapeutic equivalence code of "AP" to GLYRX-PF (glycopyrrolate) injection, 0.2 milligrams (mg) / milliliter (mL) and 0.4 mg/2 mL, approved under new drug application 210997.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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