



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

April 8, 2019

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration is requesting that the FDA assign in the Agency's Orange Book a TE Code of "AP" to GLYRX-PF with respect to West-Ward Pharmaceuticals Ltd's ("West-Ward") Robinul (glycopyrrolate injection), 0.2 mg/mL, which FDA approved under NDA 017558 prior to January 1, 1982, in addition to assign in the Agency's Orange Book a TE Code of "AP" to GLYRX-PF with respect to Somerset Therapeutics LLC's ANDA 207639 was received by this office on 04/05/2019.

It was assigned docket number FDA-2019-P-1678. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)