Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 13th Street N.W., Suite 1200
Washington, D.C. 20005-5929

Re: Docket No. FDA-2019-P-5441

Dear Mr. Karst: May 11, 2020

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 November 18, 2019 and your supplemental citizen petition received on December 2, 2019. Your petition requests that the Agency designate Polymyxin B Sulfate Injection, equivalent to 500,000 units base/vial, approved under abbreviated new drug application 202766 held by Xellia Pharmaceuticals APS as a reference standard in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.05.06 15:31:12 -04'00'

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

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