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October 14, 2020

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-5441

Dear Sir or Madam:

We write to follow-up on our Citizen Petition and Supplemental Citizen Petition submitted on November 18, 2019 and December 2, 2019, as well as our July 7, 2020 letter submitting confidential references in support. While FDA, on May 11, 2020, provided an interim response to our Citizen Petition, which requested that the Food and Drug Administration 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*, we remain eager to receive an Agency decision on this request, as it is integral to related business concerns. To that end, we write to encourage FDA to take immediate action on the Citizen Petition and Supplemental Citizen petition under Docket Number FDA 2019-P-5441.

Sincerely,

Kurt R. Karst