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March 23, 2021

BY ELECTRONIC SUBMISSION

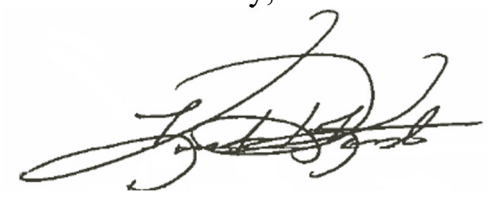
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket No. FDA 2019-P-5441

Dear Sir or Madam:

Petitioner has become aware of FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," in which FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug ("RLD") or select a reference standard ("RS"). Because the controlled correspondence pathway is now available, Petitioner requests withdrawal of the above-referenced citizen petition requesting that FDA 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. As such, a formal response to Docket No. 2019-P-5441 is no longer necessary.

Sincerely,



Kurt R. Karst