DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 18, 2019

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

Sent via email to: *kkarst@hpm.com*

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to designate ANDA 202766 (Polymyxin B sulfate Injection, EQ 500,000 units base/vial) held by Xellia Pharmaceuticals APS as a RS for purposes of FDA evaluation of ANDAs for Polymyxin B Sulfate injection, EQ 500,000 units base/vial was received by this office on 11/18/2019.

It was assigned docket number FDA-2019-P-5441. 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,

Karen Kennard -S
Digitally signed by Karen Kennard -S
Date: 2019.11.19 09:47:39 -05'00'

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)