DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 2, 2019

Kurt R. Karst
Counsel to Xellia Pharmaceutical ApS and Xellia Pharmaceuticals USA, LLC.
700 13th Street, NW Suite 1200
Washington, D.C. 20005-5929

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the FDA assign a Therapeutic Equivalance Evaluation Code ("TE Code") for the company's Vancomycin Injection, 500 mg/100 mL and 1 g/200 mL was received by this office on 04/01/2019.

It was assigned docket number FDA-2019-P-1560. 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

Digitally signed by Dynna Bigby
Date: 2019.04.03 12:40:39 -04'00'

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