FDA U.S. FOOD & DRUG ADMINISTRATION

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

Re: Docket No. FDA-2019-P-1560

SEP 27 2019

Dear Mr. Karst:

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 April 1, 2019, and submitted on behalf of Xellia Pharmaceutical ApS and Xellia Pharmaceuticals USA, LLC. Your petition requests that the Agency assign a therapeutic equivalence evaluation code for Vancomycin Injection, 500 mg/100 mL and 1 g/200 mL, which was approved on February 15, 2019, under NDA 211962.

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

U.S. Food & Drug Administration
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