DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

July 2, 2020

Kurt R. Karst
Hyman, Phelps, & McNamara, PC.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate both Vancomycin HCl for Oral Solution, 250 mg (base)/5 mL and 500 mg (base)/6 mL, approved under ANDA 061667 as RLDs1 for purposes of FDA evaluation of ANDAs for Vancomycin HCl for Oral Solution, 250mg (base)/5 mL and 500 mg (base)/6 mL was received by this office on 07/01/2020.

It was assigned docket number FDA-2020-P-1626. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Digitally signed by Karen Malvin
Date: 2020.07.02 12:13:00 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)