



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

September 30, 2013

Tish E. Pahl, Esq.  
OFW LAW  
Olsson Frank Weeda Terman Matz PC  
600 New Hampshire Avenue N.W., Suite 500  
Washington, D.C. 20037

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the Agency to determine that Vancomycin Hydrochloride USP, 1.5grams (base )/vial is suitable for an Abbreviated New Drug Application (ANDA) submission as a new strength, was received by this office on 09/27/2013. It was assigned docket number FDA-2013-P-1202/CP1, and it was filed on 09/27/2013. 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,

A handwritten signature in cursive script, reading "Karen Kennard", is written above the typed name.

Karen Kennard  
Director  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)