DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

July 11, 2013

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

Dear Mr. Karst:

Your petition to the Food and Drug Administration requesting to amend the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") to designate Ampicillin for Injection 1g and 2g in ADD-Vantage Vial approved under Abbreviated New Drug Application ("ANDA") No. 062738 as a Reference Listed Drug ("RLD"), was received by this office on 07/11/2013. It was assigned docket number FDA-2013-P-0849/CP1, and it was filed on 07/11/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)