DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

September 23, 2020

Kurt Karst Law Offices of Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street N.W. 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 declare that Potassium Chloride Extended release Tablets, 15 mEq, is suitable for submission as an ANDA was received by this office on 09/23/2020.

It was assigned docket number FDA-2020-P-2005. 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,

Dynna Bigby Supervisory Administrative Proceedings Officer Dockets Management Staff FDA/Office of Operations (OO)