DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 12, 2020

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

Sent via email to: KKarts@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to declare that Potassium Chloride Extended release for Liquid Suspension, 8 mEq and 10 mEq, are suitable for submission as an ANDA was received by this office on 11/11/2020.

It was assigned docket number FDA-2020-P-2181. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.11.12 15:41:19 -05'00'

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

Cc: dblandon@hpm.com