DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 16, 2020

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005-9329

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate NDA 022276 (Nicardipine Hydrochloride Injection, 25 mg/10 ml, Solution) as both a RLD and a RS for purposes of FDA evaluation of Abbreviated New Drug Applications (ANDAs) for Nicardipine Hydrochloride Injection, 25 mg/10 ml (2.5 mg/ml), Solution was received by this office on 01/16/2020.

It was assigned docket number FDA-2020-P-0284. 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,

Karen Malvin
Digitally signed by Karen Malvin
Date: 2020.01.17 07:58:42 -05'00'

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