DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

March 29, 2019

Mitul Chatterjee
Vice President of Regulatory Affairs
Baxter Healtcare Corporation
1 Baxter Parkway
Deerfield, Il. 60015

Sent via email to: mitul_chatterjee@baxter.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner determine whether the Reference Listed Drug CARDENE® (Nicardipine Hydrochloride Injection) 25 mg/10mL under the New Drug Application (NDA) 019734, was withdrawn for safety and/or effectiveness reasons and to designate an additional RLD was received by this office on 3/29/2019.

It was assigned docket number FDA-2019-P-1525. 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,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.05.01 09:43:38 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)