DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 28, 2020

Brendan Carroll
Alston & Bird LLP
950 F Street N.W.
Washington, DC 20004

Sent via email to: brendan.carroll@alston.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate Nicardipine Hydrochloride Premixed Injection, 0.1 mg/mL and 0.2 mg/mL, in 0.9% Sodium Chloride manufactured by Exela Pharma Sciences under NDA 022276 as alternative RLDs for the purposes of submitting an Abbreviated New Drug Application ("ANDA") for generic versions of the drug products was received by this office on 09/28/2020.

It was assigned docket number FDA-2020-P-2017. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.28 16:56:46 -04'00'

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