November 19, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Withdrawal of Nicardipine Hydrochloride Injection Citizen Petition (FDA-2020-P-2017)

Dear Sir/Madam:

A citizen petition was submitted by Alston & Bird LLP and received by FDA on September 28, 2020. An acknowledgement letter was received assigning docket number FDA-2020-P-2017 to this request.

Since the submission of the Citizen Petition, our request 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 and approved in April 2016 by FDA under 505(b)(2) process as alternative Reference Listed Drugs (RLDs), has been mooted, as FDA has now designated this product as an alternative RLD.

We therefore withdraw our Citizen Petition.

Yours truly,

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cc: Dan Jarcho, Alston & Bird LLP