Mitul Chatterjee
Vice President, Regulatory Affairs
Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015

September 17, 2020

Re: Docket No. FDA-2019-P-1525

Dear Petitioner:

This letter responds to your citizen petition received on May 6, 2019 (Petition), requesting that the Food and Drug Administration (FDA or Agency) determine whether CARDENE (nicardipine hydrochloride) injection, 25 milligrams (mg)/10 milliliters (mL), approved under new drug application 019734, was withdrawn for reasons of safety or effectiveness and to designate an additional reference listed drug (RLD). in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).[1]

On January 23, 2020, FDA issued a partial response to your petition determining that NDA 019734 was not withdrawn from sale for reasons of safety or effectiveness.

Since the time the Petition was submitted, FDA has updated the Orange Book to designate nicardipine hydrochloride injection, 25 mg/10 mL, approved under NDA 022276, as both an RLD and a Reference Standard. Therefore, we dismiss the remainder of your petition as moot.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
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Date: 2020.09.16 13:28:59 -04'00'

Patrizia Cavazzoni, M.D.
Acting Director
Center for Drug Evaluation and Research

[1] The Orange Book is available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.