FDA U.S. FOOD & DRUG ADMINISTRATION

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

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

JAN 23 2020

Dear Petitioner:

This letter responds to your citizen petition received on May 6, 2019, requesting that the Food and Drug Administration (FDA) 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hydrochloride) injection, 25 milligrams (mg)/10 milliliters (mL), approved under new drug application 019734, was withdrawn for reasons of safety or effectiveness and to designate an additional reference listed drug (RLD).

FDA has reviewed its records and determined that CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Regarding your request that FDA designate an additional RLD, FDA has not been able to reach a decision on your petition due to the need to address other Agency priorities. We will respond to that aspect of your petition as soon as possible given the numerous demands on the Agency's resources.

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination.

Sincerely,

Daniel Gottlieb
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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