FDA U.S. FOOD & DRUG ADMINISTRATION

NOV 01 2019

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

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

Dear Petitioner:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on May 6, 2019. Your petition requests that the Agency determine whether CARDENE (nicardipine hydrochloride) injection, 25 milligrams/10 milliliters, approved under new drug application 019734, was withdrawn for reasons of safety or effectiveness and to designate an additional reference listed drug (RLD).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 been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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