



U.S. FOOD & DRUG
ADMINISTRATION

Frank D. Rodriguez
Windels Marx Lane & Mittendorf, LLP
One Giralda Farms
Madison, NJ 07940

November 30, 2020

Re: Docket No. FDA-2020-P-1549

Dear Mr. Rodriguez:

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 June 10, 2020, and submitted on behalf of Annora Pharma Private Limited. Your petition requests that the Agency determine whether NYMALIZE (nimodipine), oral solution, 3 milligram (mg)/milliliter (mL), was voluntarily withdrawn from sale for safety or efficacy reasons.

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 Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research