DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 11, 2020

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

Sent via email to: frodriguez@windelsmarx.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to determine whether the Reference Listed Drug (RLD) Nymalize® (Nimodipine) Oral Solution, 3 mg/mL strength under New Drug Application (NDA) 203340 held by Arbor Pharmaceuticals LLC was voluntarily withdrawn from commercial distribution or withdrawn from sale for safety or efficacy reasons was received by this office on 06/10/2020.

It was assigned docket number FDA-2020-P-1549. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.06.12 12:49:24 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)