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June 10, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane (HFA-305)
Rockville, MD 20852

**CITIZEN PETITION**

The undersigned submits this petition on behalf of a client pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with regulations at 21 C.F.R. § 10.25(a), § 10.30(b), and § 314.161, requesting the Commissioner of Food and Drugs to provide a determination on whether a listed drug was voluntarily withdrawn for safety or effectiveness reasons as outlined below.

## A. ACTION REQUESTED

The Petitioner requests that the Commissioner of the Food and Drug Administration 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Solution, 3 mg/mL strength under New Drug Application (NDA) 203340 held by Arbor Pharmaceuticals LLC was voluntarily withdrawn from commercial distribution or withdrawn from sale for safety or efficacy reasons.

## B. STATEMENT OF GROUNDS

The Food and Drug Administration (FDA) maintains a list of drug products in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"). These drug products are eligible for submission under Section 505(j) of the FD&C Act as ANDAs. Nymalize® (Nimodipine) Oral Solution, 3 mg/mL, NDA 203340, was approved on May 10, 2013. NDA 203340, Nymalize® (Nimodipine) Oral Solution is designated as the Reference Listed Drug (RLD) by its listing in the Orange Book against which generic equivalents can be developed and approved in an ANDA. The Petitioner would like to note that Nymalize® (Nimodipine) Oral Solution, 3 mg/mL product strength was listed in the Active Section of Orange Book until recently. A Prior Approval Supplement (PAS) for Nymalize (nimodipine) oral solution (NDA 203340/S-011) requesting reformulation of Nymalize oral solution to provide a 6 mg/mL concentration of nimodipine was approved on April 8, 2020. Upon this supplemental approval, the Orange Book currently identifies Nymalize® (Nimodipine) Oral Solution, 3 mg/mL strength in the "Discontinued Drug Product List"

section of the Orange Book. Futhermore, FDA published a Summary Based Approval review[1] for the supplement approval of NDA 203340/S-011, Nymalize® (Nimodipine) Oral Solution, which identifies the discontinuation and replacement of the commercial distribution of the 3 mg/mL concentration with the new formulated 6 mg/mL concentration.

If an RLD appears in the Discontinued Section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, the applicant must submit a citizen petition under 21 C.F.R. §§ 10.25(a) and 10.30 before or at the same time as the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F .R. § 314.122(a). If the FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from the Orange Book. See 21 C.F.R. §§ 314.122, 314.161, and 314.162.

The electronic version of the Orange Book currently identifies the marketing status of the 3 mg/mL strength of Nymalize® (Nimodipine) Oral Solution, as discontinued, which is also reflected in the April 2020 Cumulative Supplement of the Orange Book. The Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of Nymalize® (Nimodipine) Oral Solution, 3 mg/mL strength under NDA 203340 was only due to commercial considerations. .

Accordingly, the Petitioner respectfully requests the FDA to confirm that the Nymalize® (Nimodipine) Oral Solution, 3 mg/mL strength was not withdrawn from sale for safety or efficacy reasons.

## C. ENVIRONMENTAL IMPACT

A claim for a categorical exclusion under 21 C.F.R. § 25.31 or environmental assessment under 21 C.F.R. § 25.40.

## D. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

## E. CERTIFICATION

The undersigned certifies to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which is unfavorable to the petition.

[1] Summary Basis of Approval for the supplement approval of NDA 203340/S-011, Nymalize® (Nimodipine) Oral Solution available at Drugs@FDA (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/203340Orig1s011.pdf)

Sincerely,

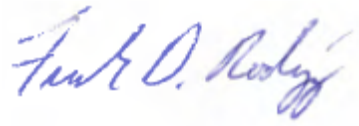

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**Exhibit- I:**
Screenshot of the electric Orange Book for Nymalize® Oral Solution (NDA 203340; Arbor Pharmaceuticals LLC) showing Marketing Status as **discontinued** for the 3 mg/ml strength.