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June 06, 2020

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

Citizen Petition

Product: Nimodipine Oral Solution 3 mg/ mL

Dear Sir/ Madam:

We intend to submit a Citizen Petition as per the 21 § C.F.R. 10.30 and in accordance with the regulations of 21 § C.F.R. 314.161, to request that the Commissioner of the Food and Drug Administration to determine whether the reference listed drug, NYMALIZE (nimodipine) oral solution 3 mg/ mL (NDA# 203340) of Arbor Pharmaceuticals LLC has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.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Administration to determine whether the drug product, NYMALIZE (nimodipine) oral solution 3 mg/ mL has been voluntarily withdrawn from sale for safety or efficacy reasons.

The petitioner believes that the NYMALIZE (nimodipine) oral solution 3 mg/ mL of Arbor Pharmaceuticals LLC was not withdrawn for the reasons of safety and efficacy.

From the Orange book and Drugs@FDA, we understand that a new concentration, NYMALIZE (nimodipine) oral solution 6 mg/mL is approved recently and it is designated with RLD and RS status. We also observed that, NYMALIZE (nimodipine) oral solution 3 mg/ mL is listed in the Discontinued Section.

After a review of publicly available information, it appears that Arbor Pharmaceuticals LLC is now marketing the product with new concentration i.e., NYMALIZE (nimodipine) oral solution 6 mg/mL and hence Arbor Pharmaceuticals LLC has withdrawn NYMALIZE (nimodipine) oral solution 3 mg/ mL, and not for safety or effectiveness reasons.

There are no published state or federal court decisions relating to product liability arising out of the use of the NYMALIZE (nimodipine) oral solution 3 mg/ mL (NDA# 203340).

The Petitioner requests the Commissioner of the Food and Drug Administration to make a determination that the discontinued formulation, NYMALIZE (nimodipine) oral solution 3 mg/ mL of Arbor Pharmaceuticals LLC was not discontinued for safety and efficacy reasons.

B. Statement of Grounds:

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications in the Approved Drug Products with Therapeutic Equivalence Evaluations ("The Orange Book"). The NYMALIZE (nimodipine) oral solution 3 mg/ mL (NDA# 203340) is currently listed in the Discontinued Section of the electronic Orange Book on FDA's website. According to the Preface to the Orange Book, a drug product in the Discontinued Section as to which a determination has already been made that withdrawal was not for safety or effectiveness reasons will include the following statement after its product strength: "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons." There is no such annotation for NYMALIZE (nimodipine) oral solution 3 mg/ mL (NDA# 203340) in the Orange book. The petitioner asks the FDA to determine that the NDA holder, Arbor Pharmaceuticals LLC voluntarily withdrew the NYMALIZE (nimodipine) oral solution 3 mg/ mL (NDA# 203340) from sale for reasons other than safety or effectiveness.

After a review of publicly available information, it appears that Arbor Pharmaceuticals LLC is now marketing the product with new concentration i.e., NYMALIZE (nimodipine) oral solution 6 mg/mL and hence Arbor Pharmaceuticals LLC has withdrawn NYMALIZE (nimodipine) oral solution 3 mg/ mL, and not for safety or effectiveness reasons.

There are no published state or federal court decisions relating to product liability arising out of the use of the NYMALIZE (nimodipine) oral solution 3 mg/ mL (NDA# 203340).

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 § C.F.R. 314.161(a)(1)).

The available information suggests that the NYMALIZE (nimodipine) oral solution 3 mg/ mL was not withdrawn for safety or effectiveness reasons. Rather, it appears that Arbor Pharmaceuticals LLC withdrew NYMALIZE (nimodipine) oral solution 3 mg/ mL for voluntary reasons unrelated to the product's safety or effectiveness.

The Petitioner, therefore, requests that the FDA determine that Arbor Pharmaceuticals LLC voluntary withdrawal of NYMALIZE (nimodipine) oral solution 3 mg/ mL from sale was for reasons other than safety or effectiveness in order to enable action on an ANDA referring to NYMALIZE (nimodipine) oral solution 3 mg/ mL product as the Reference Listed Drug. It also requests that the Agency publish a notice of its determination in the Federal Register and to appropriately annotate the Orange Book.

Should the NDA holder recommence marketing its NYMALIZE (nimodipine) oral solution 3 mg/ mL after the submission of this petition and prior to an FDA response, and there is evidence that the product is available in the marketplace, the petitioner will consider this petition.

C. Environmental Impact:

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact:

Pursuant to 21 C.F.R. § 10.30(b}, economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification:

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The undersigned certifies that, 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 petition which is unfavorable to the petition.

References/Attachments:

1. Orange Book_ Nimodipine Oral Solution
2. sNDA approval package for 6 mg per mL (new concentration)
3. Notice of Formulation Change by Arbor Pharmaceuticals LLC
4. Package insert for 3 mg per mL
5. Package insert for 6 mg per mL (new concentration)

Sincerely,

Soma Raju, Ph.D
US Agent - Regulatory Affairs