



Frank D. Rodriguez  
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One Giralda Farms  
Madison, NJ 07940

February 17, 2021

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

Dear Mr. Rodriguez:

This letter responds to your citizen petition received on June 10, 2020, requesting that the Food and Drug Administration (FDA) determine whether Nymalize (nimodipine), oral solution, 3 milligram (mg)/milliliter (mL), has been voluntarily withdrawn from commercial distribution or withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Nymalize (nimodipine), oral solution, 3 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Nymalize (nimodipine), oral solution, 3 mg/mL, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-4191.

Sincerely,

Ayako Sato  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure