



Soma Raju, Ph.D
U.S. Agent – Regulatory Affairs
Annora Pharma Private Limited
Sy. No. 261, Annaram Village
Gummadidala Mandal, Sangareddy Dist
Telangana State 502 313, India

February 17, 2021

Re: Docket No. FDA-2020-P-1511

Dear Dr. Raju:

This letter responds to your citizen petition received on June 6, 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(FDA) determine whether Nymalize (nimodipine), oral solution, 3 milligram (mg)/milliliter (mL), has been voluntarily withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Nymalize (nimodipine), oral solution, 3 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness.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