



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 08, 2020

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

Sent via email to venkat@graceconsultingusa.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to determine whether the drug product, NYMALIZE (nimodipine) oral solution 3 mg/mL has been voluntarily withdrawn from sale for safety or efficacy reasons was received by this office on 06/05/2020.

It was assigned docket number FDA-2020-P-1511. 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 Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)