December 12, 2022

Kurt Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Washington, D.C. 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your submission requesting that the Commissioner to determine whether MYSOLINE primidone Suspension 250 mg/5 mL approved under New Drug Application NDA number 010401 held by Nuro Pharma LLC has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 12/08/2022.

It was assigned docket number FDA-2022-P-3118. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.12.12 10:19:35 -05'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)