Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street NW
Suite 1200
Washington, DC 20005

June 5, 2023

Re: Docket No. FDA-2022-P-3118

Dear Mr. Karst:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 8, 2022. Your petition requests that the Agency determine whether MYSOLINE (primidone) Suspension, 250 mg/5mL, approved under New Drug Application number 010401 and held by Nuro Pharma LLC, has been withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2023.06.05 10:13:02 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research