U.S. FOOD & DRUG ADMINISTRATION

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 13th St. NW, Suite 1200
Washington, DC 20005

July 8, 2022

Re: Docket No. FDA-2022-P-0068

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 January 11, 2022. Your petition requests that the Agency determine whether ENDEP (amitriptyline HCl) Oral Concentrate, 40 milligrams/milliliter, approved under Abbreviated New Drug Application number 085749, held by Hoffmann-La Roche Inc, has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S Digitally signed by Carol Bennett -S
Date: 2022.07.08 10:50:09 -04'00'

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov