Michael T. Abrams, M.P.H., Ph.D.
Senior Health Researcher
Public Citizen's Health Research Group
1600 20th St. N.W.
Washington, DC 20009

August 4, 2022

Re: Docket No. FDA-2022-P-0149

Dear Dr. Abrams:

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 February 8, 2022. Your petition requests that the Agency place gabapentin (2-[1-(aminomethyl) cyclohexyl] acetic acid), including its salts, and all products containing gabapentin, and gabapentin enacarbil (1-{[({(1RS)-1-[(2-methylpropanoyl)oxy]ethoxy} carbonyl)amino]methyl} cyclohexyl) acetic acid), including its salts into schedule V of the Controlled Substances Act.

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: 2022.08.04 09:08:05 -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