

U.S. Department of JusticeDrug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

Public Citizen 1600 20th Street, N.W. Washington, D.C. 20009

Dear Public Citizen:

This letter is in response to your petition dated February 9, 2022, requesting that the Drug Enforcement Administration (DEA) place (a) gabapentin (2-[1-(aminomethyl) cyclohexyl] acetic acid), including its salts, and all products containing gabapentin (including the brand name products Gralise and Neurontin) and (b) gabapentin enacarbil (1-{[({(1RS)-1-[(2-ethylpropanoyl)oxy]ethoxy carbonyl)amino]methyl}cyclohexyl)acetic acid), including its salts, (including the brand name product Horizant) into schedule V of the Controlled Substances Act (CSA). DEA has determined that your petition to schedule gabapentin under the CSA complies with the requirements of 21 CFR 1308.43(b), and accordingly accepts this petition for filing.

With respect to gabapentin enacarbil, DEA has determined that the data provided to support the scheduling of this drug is insufficient and therefore the petitioner's request to initiate proceedings to review the control of gabapentin enacarbil is denied. However, DEA invites the petitioner to resubmit the petition to schedule gabapentin enacarbil and include data which specifically indicates the pharmacological profile, abuse potential, and the threat to public safety for this substance.

If you have additional information or questions, please contact Mr. Eric Triana, Deputy Assistant Administrator, Diversion Control Division, at (571) 776-3998.

Sincerely,

Kristi O'Malley Assistant Administrator Diversion Control Division