DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 9, 2022

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Sent via email to: mabrams@citizen.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug promptly initiate the proceedings to 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-methylpropanoyl)oxy]ethoxy} carbonyl)amino]methyl} cyclohexyl) acetic acid), including its salts, (including the brand name product Horizant) into schedule V of the CSA was received and processed under CFR 10.30 by this office on 02/08/2022.

It was assigned docket number FDA-2022-P-0149. Please refer to this docket number in future correspondence on this subject with the Agency.

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

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.10 13:55:25 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)