May 4, 2020

Michael A. Carome, M.D., Director
Sidney M. Wolfe, M.D., Founder and Senior Adviser
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Delaram J. Taghipour, M.D.
Resident, General Preventive Medicine
Johns Hopkins Bloomberg School of Public Health

Re: Docket No. FDA-2019-P-5268

Dear Drs. Carome, Wolfe and Taghipour:

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 November 6, 2019. Your petition requests that the Agency immediately initiate proceedings to reschedule 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, its optical and geometric isomers, and salts of these isomers (including tramadol) from schedule IV to schedule II of the Controlled Substances Act.

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
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Date: 2020.05.04 13:41:39 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
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