



Sidney M. Wolfe, MD
Michael A. Carome, MD
Public Citizen
1600 20th Street, NW
Washington, D.C. 20009

December 18, 2020

Re: Docket No. FDA-2020-P-1611

Dear Drs. Wolfe and Carome:

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 June 24, 2020, and submitted on behalf of Public Citizen and Public Citizen's Health Research Group. Your petition requests that the Agency require the addition of a boxed warning to the labeling for all sodium-glucose cotransporter-2 inhibitor drug products contraindicating their use in patients with type 1 diabetes mellitus, as well as other related labeling changes.

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 -
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Digitally signed by Carol Bennett -S
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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director

Office of Regulatory Policy
Center for Drug Evaluation and Research