



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

June 24, 2020

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

Sent via email to: swolfe@citizen.org, mcarome@citizen.org

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to require a boxed warning for all sodium-glucose cotransporter-2 (SGLT2) inhibitor drugs contraindicating their use in patients with type 1 diabetes mellitus (hereafter, diabetes) was received by this office on 06/24/2020, and it was assigned docket number FDA-2020-P-1611. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
OC/Office of Operations (OO)