



Lem Moyé, M.D., Ph.D

(b) (6)

April 28, 2023

Re: Docket No. FDA-2022-P-2708

Dear Dr. Moyé:

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 1, 2022. Your petition requests that the Agency reexamine the results of the DECLARE clinical trial, with particular attention to the use of the combined endpoint of cardiovascular death and hospitalization for heart failure.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett

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Digitally signed by Carol
Bennett-S
Date: 2023.04.27 09:21:33
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research