



November 1, 2022

Lem Moyé

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Sent via email to: (b) (6)

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug 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 was received and processed under CFR 10.30 by this office on 11/01/2022.

It was assigned docket number FDA-2022-P-2708. 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 the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)