



January 22, 2021

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Dear Dr. Michael Carome,

Thank you for your December 9, 2020 letter to Dr. Stephen Hahn and Dr. Patrizia Cavazzoni regarding Aducanumab for the treatment of Alzheimer's disease. Your letter was received by Dr. Cavazzoni and referred to the Center for Drug Evaluation and Research (CDER) for a response.

The agency thanks you for your letter raising certain concerns regarding a pending biologics license application for Aducanumab for the treatment of Alzheimer's disease and a related Peripheral and Central Nervous System Advisory Committee meeting and requesting that CDER take certain actions in response to your stated concerns. We are sharing this with the appropriate individuals within CDER for further consideration.

Please know that we continuously strive to fulfill our mission of protecting and promoting public health by ensuring safe and effective drugs are available to patients.

Thank you, again, for sharing your concerns with us regarding this matter.

Sincerely,

Patrizia Cavazzoni, M.D.
Acting Director
Center for Drug Evaluation and Research