DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

July 20, 2021

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

Dear Dr. Carome:

Thank you for your letters dated June 30 and July 13, 2021, to Principal Deputy Inspector General Christi A. Grimm of the Office of Inspector General (OIG), Department of Health and Human Services (HHS), which followed up on a previous letter you sent OIG regarding collaboration between the Food and Drug Administration and Biogen related to the company's biologics license application for its Alzheimer's disease drug Aduhelm (aducanumab). I am responding on behalf of the Principal Deputy Inspector General.

OIG appreciates the additional information you forwarded and will review carefully your request along with the other requests that we have received related to FDA's approval of Aduhelm. Safeguarding public health is a top priority for OIG. We provide extensive oversight of HHS's programs, including work that identifies opportunities to, among other things, ensure the integrity of agency review and decision making. As with all requests, we will assess these against our jurisdictional limitations as well as our oversight priorities. OIG identifies the work that we are undertaking through our Work Plan, which can be found on the OIG website. Any work that OIG undertakes related to FDA's approval of Aduhelm will be included in the Work Plan. Again, we appreciate your sharing information on an important topic and your interest in our oversight work.

Sincerely,

Christopher S. Seagle
Director, External Affairs