DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

January 11, 2021

Michael A. Carome, M.D.
Director
Public Citizen, Health Research Group
215 Pennsylvania Avenue, SE
Washington, DC 20003

Dear Dr. Carome:

Thank you for your letter dated December 9, 2020, to Principal Deputy Inspector General Christi A. Grimm of the Office of Inspector General (OIG), Department of Health and Human Services (HHS), regarding collaboration between the Food and Drug Administration (FDA) and Biogen before and after submission of that company's biologics license application (BLA) for its Alzheimer's disease drug aducanumab. I am responding on behalf of the Principal Deputy Inspector General.

In your letter, you request that OIG investigate FDA's collaboration with Biogen that occurred before and after the submission of Biogen's aducanumab BLA. You assert that this collaboration was unprecedented in its closeness, compromising the integrity of the FDA's regulatory review and decision making.

Safeguarding public health is one of the Department's Top Management and Performance Challenges, and OIG has responded by focusing on work that identifies opportunities to, among other things, ensure the integrity of agency review and decision making. OIG continuously engages in work planning and will include the collaboration issues you have raised in our ongoing work planning discussions.

Sincerely,

Christopher S. Seagle
Director, External Affairs