Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852  
May 24, 2016

To Whom It May Concern,

On behalf of the Alzheimer’s Association, I write to express our support for the Food and Drug Administration’s (FDA) draft guidance on Investigational Device Exemptions for Neurological Devices Targeting Disease Progression and Clinical Outcomes. FDA must maintain the same high quality evidentiary standards for devices that are applied to the drug approval process and we believe this guidance promotes such standards. With specific information on study design and submission, this guidance may expedite safe, effective devices to market, improving patients’ quality of life.

Thank you for the opportunity to comment. The Alzheimer’s Association is glad to serve as a resource to FDA as it considers these important issues and how they relate to individuals living with Alzheimer’s and related dementias. Please contact Laura Thornhill, Manager of Regulatory Affairs, at 202-638-7042 or lthornhill@alz.org if you have questions or if we can be of additional assistance.

Sincerely,

Robert Egge  
Executive Vice President, Government Affairs