DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 13, 2006

Daniel Perry
Executive Director
Alliance for Aging Research
2021 K Street N.W., Suite 305
Washington, D.C. 20006

Dear Mr. Perry:

Thank you for meeting with me and my staff on July 24. We appreciated and valued the opportunity to learn about the efforts of the Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) Coalition.

At the July meeting, you outlined why AD deserves the Food and Drug Administration's (FDA's) focus, expressed interest in collaborating with FDA on scientific and public meetings to discuss AD drug development issues, and stressed the importance of including patient advocates in FDA's drug review process. I know that David Banks in the Office of Special Health Issues and Terry Toigo, Assistant Commissioner for Special Health Issues, have talked with you since our meeting and I encourage you to continue dialogue with that office. In this letter, I would like to update you on some of the agency's progress on issues discussed at our July meeting.

To improve neurological disease communication across FDA, neurological disease experts involved in the regulation of drugs, biologics, and medical devices have established an FDA Intra-agency Neurology Working Group to conduct regular meetings about neurological issues. The group is chaired by Dr. Celia Witten of the Center for Biologics Evaluation and Research and Dr. Robert Temple of the Center for Drug Evaluation and Research and will focus broadly on technical and regulatory issues across neurology. These enhanced lines of communication will:

- expand FDA awareness of leading-edge developments,
- enable sharing of technical and regulatory expertise, and
- provide for greater consistency of review standards and processes across FDA.

The agency anticipates that the knowledge and information sharing in this group will improve FDA's ability to facilitate development of medical products to diagnose and treat AD and other serious neurological diseases. David Banks will serve as the FDA contact point for patient advocacy organizations interested in raising issues for consideration by this group.

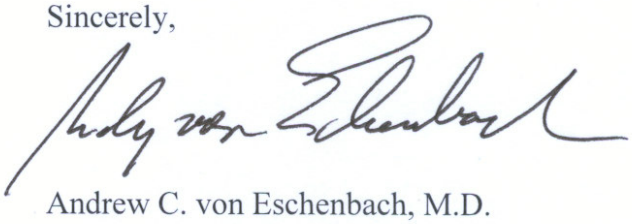
Medical product sponsors will continue to work primarily with the medical product review divisions with review responsibility for their applications.

To facilitate patient advocate participation in FDA's regulation of the development of new treatments for serious neurological diseases, the agency is expanding its existing Patient Consultant program to include AD. Through this program, AD advocates will advise FDA during development of new medical products. AD advocates will also be invited, through FDA's Patient Representative Program, to participate in FDA advisory committee meetings advising FDA with respect to marketing approval decisions and in response to issues arising with marketed products.

As the "baby boom" generation ages, the number of people affected by age-related neurological disease is growing rapidly. We must do all we can to maximize the quality and productivity of FDA's work to facilitate development of new treatments across the spectrum of neurological diseases. FDA applauds the ACT-AD Coalition's interest in working "in partnership with government and science to bring new treatments to patients and their families within the next decade."

The agency welcomes the eagerness of the AD patient advocacy community to contribute to FDA's important work, and it appreciates your involvement.

Sincerely,



Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs