



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

November 13, 2006

Bonnie Hogue Duffy, MA  
Director of Federal Policy  
Alzheimer's Association  
1319 F Street N.W., Suite 500  
Washington, D.C. 20004

Dear Ms. Duffy:

Thank you to you and your colleagues for meeting with me and my staff on August 3. We appreciated and valued the opportunity to learn about the ongoing activities of the Alzheimer's Association.

At the August meeting, you outlined why Alzheimer's Disease (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 August 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.

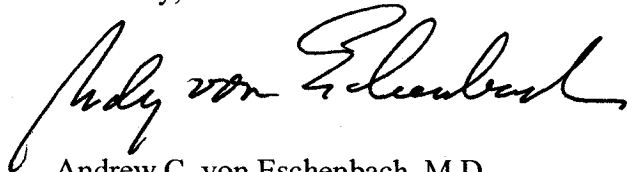
Medical product sponsors will continue to work primarily with the medical product review divisions with review responsibility for their applications.

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 mission of the Alzheimer's Association "to eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health."

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

Sincerely,

A handwritten signature in black ink, reading "Andrew C. von Eschenbach". The signature is written in a cursive style with a large, sweeping initial "A".

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

**Williams, Paul**

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**From:** Caldwell, LaJuana D  
**Sent:** Friday, November 03, 2006 9:53 AM  
**To:** Williams, Paul  
**Subject:** FW: July 24 ACT-AD meeting summary  
**Attachments:** alzheimerletterperry.doc; alzheimerletterduffy.doc

Paul,  
Please have these logged in and assigned

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**From:** Toigo, Theresa A  
**Sent:** Thursday, November 02, 2006 9:37 PM  
**To:** Caldwell, LaJuana D  
**Cc:** Banks, David; Whalen, Michele  
**Subject:** RE: July 24 ACT-AD meeting summary

LaJuana,

Attached are two letters for ExSec review and clearance by CDER, CDRH, and CBER. At a meeting on Tuesday, October 31, reps from the centers and OSHI {Celia Witten, MD (CBER), Robert Temple, MD (CDER), Theresa Toigo (OSHI), Dave Banks, PhD (OSHI), Russell Katz, MD (CDER), Carlos Pena, PhD, MS (CDRH), Ashok Batra, MD (CBER), Ellen Maher, MD (CBER), Colleen LoCicero (CDER)} participated in a telephone call to discuss the working group and contents of the letter.

Dr. von Eschenbach is speaking at an Alzheimer's forum on November 14. At this time the plan is to have the letters issue prior to the meeting.

Please let me know if you need additional information from me. Thank you.

Terry

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**From:** Caldwell, LaJuana D  
**Sent:** Thursday, October 26, 2006 11:50 AM  
**To:** Toigo, Theresa A  
**Subject:** July 24 ACT-AD meeting summary

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**From:** Jackson, Valerie  
**Sent:** Thursday, October 26, 2006 11:50 AM  
**To:** Caldwell, LaJuana D  
**Subject:**