

Peripheral and Central Nervous System Drugs Advisory Committee

Proposed Agenda for March 14, 2001

Drug Development: Vascular Dementia

8:00 am – 10:00am On March 14, 2001, the committee will listen to discussants and discuss drug development for individuals with **vascular dementia**. While vascular dementia is considered by some to be a distinct entity others do not agree that it can be easily distinguished from Alzheimer's Disease and/or other dementias. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully explored. We will explore the following types of questions:

1. Can vascular dementia be clearly defined in a clinical setting?
2. Are there valid criteria for the diagnosis of vascular dementia?
3. Can vascular dementia be distinguished from Alzheimer's Disease and other causes of dementia?
4. What outcome measures are appropriate to use in clinical drug trials conducted in vascular dementia?
5. Should clinical drug trials in vascular dementia incorporate any special features in their design?

FDA will provide a Background Position Paper on vascular dementia. When the background material becomes available, it will be posted at this web site.

10:30am – 12:30 pm: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 1, 2001. On March 14 oral presentations from the public will be scheduled from approximately 10:30 a.m. – 12:30 p.m. Time allotted for each presentation may be limited. Please contact Sandra Titus, Ph.D., at 301-827-7001 to discuss your interest.

1:30 – until we end Discussion by the Committee