FDA Advisory Committee Discussion of Drug Development

for Treating Psychiatric Disturbances Associated with Dementias

The FDA has tentatively scheduled a meeting of the Psychopharmacologic Drugs Advisory Committee for March 9, 2000 starting at 8 a.m. at the Holiday Inn in Gaithersburg Maryland. Please check the Federal Register notices for the official announcement of this meeting.

The committee will discuss the best way to develop drugs for the treatment of the various psychiatric and behavioral disturbances that are frequently associated with Alzheimer's disease and other dementias. In particular, the presentations and discussions will focus on the problem of how to identify, define, and name the clinical entities that fall under this broad category of disorders. This is a major regulatory issue because the failure to adequately define specific disorders in this area could lead to misleading labeling.

As background information for this meeting, FDA has provided an Issues Paper found at: (**DOCKET 00N-0088 at http://www.fda.gov/ohrms/dockets/dockets/00N-0088/00N-0088.htm)** that describes in detail the regulatory issues and concerns, and proposes how this question might be addressed. This Issues Paper is intended to serve as a stimulus for others in the community of clinicians, academicians, and pharmaceutical sponsors to articulate and submit alternative positions in response to this question. Written statements should be submitted by February 17, 2000, by following the procedures listed below. Statements submitted by this date will be made available on above web site. Written submissions may be made to Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. These submissions should contain **docket number 00N-0088,** and should be received by February 17, 2000.

In addition to providing written statements, those interested in this issue are invited to make presentations of up to 10 minutes in an expanded open public session at the March 9, 2000, meeting. Oral presentations from the public will be scheduled between approximately 10 a.m. to 12:30 p.m. Additional time may be allocated. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 17, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Please contact Sandra Titus, Ph.D., Food and Drug Administration, Center for Drug Evaluation and Research (HFD-21), 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, 301-827-7001, or e-mail Tituss@cder.FDA.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.