DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

ACTION: Notice.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 9, 2000, 8 a.m. to 4:30 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sandra L. Titus or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 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.

Agenda: 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 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 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. Interested persons may submit written statements by February 17, 2000. Written statements submitted by the above date will be made available on FDA's website identified above. In addition to submitting written statements, interested persons are invited to make presentations of up to 10 minutes in an expanded open public session at the March 9, 2000, meeting. Those persons interested in making a presentation should follow the procedures given in the *''Procedure''* section below.

Procedure: 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 Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These submissions should contain Docket No. 00N–0088, and should be received by February 17, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 12:30 p.m. Additional time may be allocated for oral presentations. Time allotted for each presentation may be limited to 10 minutes. 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–2861 Filed 2–8–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0084]

Draft Guidance for Industry on Special Protocol Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Special Protocol Assessment.'' This draft guidance is intended to provide guidance for industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies.

DATES: Submit written comments on the draft guidance and the collection of information provisions by April 10, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Special Protocol Assessment.'' The draft guidance is intended to provide guidance for industry on procedures that will be adopted by CDER and CBER to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. This draft guidance describes procedures for sponsors to request