breakout discussion groups. There is no registration fee for this workshop. Registration forms can be obtained by calling 301–443–5470 or writing to the Office of Health Affairs, ATTN: Patient Education Workshop, Food and Drug Administration (HFY-40), 5600 Fishers Lane, Rockville, MD 20857. Submit written views or comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The designers of information systems should call the contact person (address below) for registration information. A more detailed agenda and written presentations will be placed in the docket, identified with the docket number found in brackets in the heading of this document, at the Dockets Management Branch, and will be available for review between 9 a.m. and 4 p.m., Monday through Friday. A transcript of the general sessions of the workshop will be available for review or purchase (10 cents per page) at the **Dockets Management Branch** approximately 5 business days after the meeting. The breakout sessions will not be transcribed.

FOR FURTHER INFORMATION CONTACT: Thomas J. McGinnis, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857, 301-443-5470. SUPPLEMENTARY INFORMATION: In the Federal Register of August 24, 1995 (60 FR 44182), FDA published a proposed rule which, if finalized, is intended to increase the dissemination of useful written prescription drug information to patients who receive prescription drugs on an outpatient basis. The agency believes that such information must be widely distributed and be of sufficient quality to promote the proper use of prescription drugs. The agency proposed goals (performance standards) that would define acceptable levels of information distribution and quality. To meet the performance standard for distribution of patient information, the agency proposed that by the year 2000, at least 75 percent of people receiving new prescriptions receive useful written information. This goal was adapted from the Public Health Service's "Healthy People 2000" report. In addition, the agency proposed that by the year 2006, at least 95 percent of the people who receive new prescriptions receive useful written information.

FDA proposed to periodically evaluate and report on the achievement of the goals. If the goals are not met in the specified timeframes, FDA proposed to either: (1) Implement a mandatory

comprehensive medication guide program, or (2) seek public comment on whether the comprehensive program should be implemented, or whether, and what, other steps should be taken to meet the patient information goals.

In the Federal Register of August 24, 1995, the agency proposed the following seven specific components for determining whether patient information is useful: Scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility. The agency defined these components of usefulness, as well as criteria that could be used to judge these components, and invited comments on their appropriateness. The agency also stated that it would hold a public meeting for interested parties to provide recommendations and rationale for evaluating usefulness of written information.

The agency will hold a public patient education workshop to discuss the methods and criteria for developing and evaluating the usefulness of written information. The patient education workshop will be designed to obtain recommendations from the public about the criteria that should be applied to help ensure that written information provided to patients is "useful."

The patient education workshop will be comprised of both formal presentations and open breakout discussion periods. Any interested person may attend and participate in the discussions. The workshop will include general sessions with presentations from FDA, health professional groups, consumer groups, the pharmaceutical industry, academicians, and parties with legal and regulatory expertise. The agency also intends to hold breakout sessions throughout the 2-day workshop to obtain broad participation and input from workshop attendees.

FDA believes that it would be helpful for workshop participants (including FDA staff) to learn about the design of current patient information systems, in particular, programs that generate drugspecific patient information. The agency invites the designers of primary information systems (not the customizers of systems for retail outlets) to display their systems at the workshop for educational purposes only. No sales or solicitations may be made by exhibitors at the workshop site. Due to space limitations, FDA may be forced to limit the number of systems on display. In doing so, FDA would seek to permit display of the most representative/ comprehensive systems available for patient information. However, the

agency invites all interested persons to submit their views, comments, and descriptions of computer programs to the Dockets Management Branch (address above).

The agency notes that the comment period for the proposed rule that published in the Federal Register of August 24, 1995, has recently been extended until December 22, 1995 (60 FR 58025, November 24, 1995). Because this workshop will occur after the comment period has closed, the agency will accept additional comments to the proposed rule on the specific issues raised at the workshop. These comments will be considered as part of the agency's deliberations regarding further action on this rulemaking. For this limited purpose, written comments may be submitted to the Dockets Management Branch (address above) until January 31, 1996. Comments are to be identified with the docket number found in brackets in the heading of this document.

A summary of the workshop will be included in a subsequent Federal Register notice related to this prescription drug labeling initiative.

Dated: December 1, 1995.
William K. Hubbard,
Associate Commissioner for Policy.
[FR Doc. 95–29903 Filed 12–7–95; 8:45 am]
BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel. Date: December 11, 1995.

Time: 11 a.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857. Contact Person: Michael D. Hirsch,

Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857,

Telephone: (301) 443-1000.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.