

pending before an Administrative Law Judge.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 95-16256 Filed 6-30-95; 8:45 am]

BILLING CODE 6750-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

#### White House Conference on Aging

**AGENCY:** White House Conference on Aging, AoA, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** Notice is hereby given, pursuant to Title II of the Older Americans Act Amendments of 1987, Pub. L. 100-175 as amended by Pub. L. 102-375 and Pub. L. 103-171, that the 1995 White House Conference on Aging Business Advisory Committee will meet on Monday, July 17, 1995 from 10:00 AM-noon in the Hubert H. Humphrey Building at 200 Independence Avenue, SW in Washington, DC. Information on the specific room in which the meeting will be held can be obtained by calling the telephone number given below. The meeting of the Committee shall be open to the public.

The proposed agenda includes discussion of how the Committee and the business community can assist with implementation of the resolutions adopted by the Conference delegates. Records shall be kept of all Committee proceedings and shall be available for public inspection at 501 School Street, SW, 8th Floor, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** White House Conference on Aging, 501 School Street, SW, 8th Floor, Washington, DC 20024; telephone (202) 245-7116.

**Fernando M. Torres-Gil,**

*Assistant Secretary for Aging.*

[FR Doc. 95-16270 Filed 6-30-95; 8:45 am]

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### Agency for Health Care Policy and Research

#### Health Care Policy and Research Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5

U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of August 1995:

Name: Health Care Policy and Research Special Emphasis Panel

Date and Time: August 10, 1995, 8:30 a.m.

Place: Hyatt Regency, One Bethesda Metro Center, Conference Room TBA, Bethesda, MD 20814.

Open August 10, 8:30 a.m. to 9 a.m. Closed for remainder of meeting.

#### Purpose

This panel is charged with conducting the initial review of grant applications proposing health services research training programs under the National Research Service Awards Program.

#### Agenda

The open session of the meeting on August 10, from 8:30 a.m. to 9 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), it has been determined that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Linda W. Blankenbaker, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1438.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: June 26, 1995.

**Clifton R. Gaus,**

*Administrator.*

[FR Doc. 95-16253 Filed 6-30-95; 8:45 am]

BILLING CODE 4160-90-M

### Food and Drug Administration

[Docket No. 92N-0371]

#### New Drug Applications; Refusal to File; Change in Procedures to Include Industry Representatives in Meetings of the Review Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a change in the review process conducted

by the Center for Drug Evaluation and Research's (CDER's) Refusal to File (RTF) review committee. The new procedures will permit applicants that have received an RTF to attend the meeting at which the RTF review committee evaluates the RTF imposed on its application. This change, which will be implemented on a trial basis, may enhance understanding of and participation in the RTF review committee process. Additional changes to the procedures may be useful and comments are requested.

**DATES:** Comments may be submitted at any time.

**ADDRESSES:** Submit written comments on this change in procedures to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Janet M. Jones, Center for Drug Evaluation and Research (HFD-014), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5445.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 18, 1993 (58 FR 28983), FDA announced the establishment of a standing committee in CDER's to conduct periodic review of the CDER's RTF decisions. The committee was established on a 1-year trial basis. Initially, the committee invited companies to submit requests for review of RTF's that they considered to have been made inappropriately. The RTF review committee consists of senior CDER officials, a senior official from the Center for Biologics Evaluation and Research, and FDA's Chief Mediator and Ombudsman.

CDER created the RTF review committee because it believes that a clear, well-understood, and consistently applied RTF policy may improve substantially the efficiency of the new drug evaluation process. The practice of submitting an incomplete or inadequate application and then providing additional information during an extended review period is inherently inefficient and a waste of agency resources. In addition, it is unfair to those applicants who fulfill their scientific and legal obligations by submitting complete applications to have the review of their applications delayed while other incomplete applications submitted earlier undergo review and repair.

FDA regulations on filing applications, including grounds and procedures for RTF's, are found in § 314.101 (21 CFR 314.101). In the past, some CDER review divisions refused to