

Agency for Health Care Policy and Research (AHCPR), the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA), the National Institutes of Health (NIH), and the Office of Public Health and Science (OPHS), serve on the Board. This public meeting will have two purposes:

1. Members of the Orphan Products Board will discuss their agencies recent orphan product development activities.

2. In keeping with its mandate to foster actions within the Department of Health and Human Services to facilitate the research, development, and approval of orphan products and to coordinate Government activities with the private sector in order to achieve these goals, the board encourages presentations by members of the public on any issues involving the development and availability of orphan products. Those persons wishing to make a presentation at the meeting should submit a written request for a time slot to the Executive Director of the Orphan Products Board. The request for participation should be submitted before February 4, 1998, and should include: (a) Name, address, and telephone number of the person desiring to make a presentation; (b) affiliation, if any; (c) a summary of the presentation; and (d) the approximate amount of time required for the presentation (no more than 10 minutes, unless more time can be justified).

Individuals and organizations with common interests or proposals are urged to coordinate or consolidate their presentations. Joint presentations may be required of persons or organizations with a common interest. The time available will be allocated among the individuals who request an opportunity for a presentation. Formal written statements or extensions of remarks (five copies) should be presented to the Executive Director on the day of the meeting for inclusion in the record of the meeting. At the discretion of the Chairman, and as time permits, any person in attendance may be heard. This time will, most likely, be at the end of the scheduled session. For those unable to attend the meeting, comments may be sent to the listed contact person.

Dated: December 18, 1997.

John M. Eisenberg,

Acting Assistant Secretary for Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency For Health Care Policy and Research

Notice of 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 January 1998:

Name: Health Care Policy and Research Special Emphasis Panel.

Date and Time: January 6-7, 1998, 8:00 a.m.

Place: Doubletree Hotel, 1750 Rockville Pike, Rockville Room, Rockville, MD 20852. Open January 6, 8:00 a.m. to 8:30 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 January 6, from 8:00 a.m. to 8:30 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, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, Agency for Health Care Policy and Research, has made a formal determination 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 Sheila Simmons, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland, 20852, Telephone (301) 594-1452 x 1627.

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

Dated: December 22, 1997.

John Eisenberg,

Administrator.

[FR Doc. 97-33870 Filed 12-29-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0446]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse drug experience reporting and recordkeeping requirements.

DATES: Submit written comments on the collection of information by March 2, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB