

each age category; a summary of the information submitted to support the pediatric labeling statements and an integrated summary of the pediatric safety data with a risk/benefit assessment; and presentation of the data.

Although this guidance does not create or confer any rights for or on any person and does not operate to bind FDA, it does represent the agency's current thinking on how to prepare "pediatric use" labeling supplements for submission to FDA.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. If written comments demonstrate that changes to the guidance are appropriate, such changes to the guidance will be made.

Dated: May 17, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-13175 Filed 5-23-96; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Clinical Sciences.

Date: May 30, 1996.

Time: 8:30 a.m.

Place: NIH, Natcher Bldg., Bethesda, MD.

Contact Person: Dr. Ronald Suddendorf, Scientific Review Administrator, 6000 Executive Blvd., Room 409, Bethesda, Maryland 20892, (301) 443-2926.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of SEP: Biological and Physiological Sciences.

Date: June 4, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 5146, Telephone Conference.

Contact Person: Dr. Ramesh Nayak, Scientific Review Administrator, 6701 Rockledge Drive, Room 5146, Bethesda, Maryland 20892, (301) 435-1026.

Name of SEP: Biological and Physiological Sciences.

Date: June 17, 1996.

Time: 8:00 a.m.

Place: Bethesda Marriott Hotel, Bethesda, MD.

Contact Person: Dr. Nabeeh Mourad, Scientific Review Administrator, 6701 Rockledge Drive, Room 5110, Bethesda, Maryland 20892, (301) 435-1168.

Name of SEP: Clinical Sciences.

Date: June 19-20, 1996.

Time: 8:00 a.m.

Place: Residence Inn, Bethesda, MD.

Contact Person: Dr. Josephine Pelham, Scientific Review Administrator, 6701 Rockledge Drive, Room 4106, Bethesda, Maryland 20892, (301) 435-1786.

Name of SEP: Behavioral and Neurosciences.

Date: July 10, 1996.

Time: 8:30 a.m.

Place: Holiday Inn, Bethesda, MD.

Contact Person: Dr. Carl Banner, Scientific Review Administrator, 6701 Rockledge Drive, Room 5182, Bethesda, Maryland 20892, (301) 435-1251.

Name of SEP: Clinical Sciences.

Date: October 23-24, 1996.

Time: 8:00 a.m.

Place: Residence Inn, Bethesda, MD.

Contact Person: Dr. Josephine Pelham, Scientific Review Administrator, 6701 Rockledge Drive, Room 4106, Bethesda, Maryland 20892, (301) 435-1786.

Purpose/Agenda: To review Small Business Innovation Research.

Name of SEP: Multidisciplinary Sciences.

Date: June 5, 1996.

Time: 1:00 p.m.

Place: Rosslyn Westpark Holiday Inn, Arlington, VA.

Contact Person: Dr. Lee Rosen, Scientific Review Administrator, 6701 Rockledge Drive, Room 5116, Bethesda, Maryland 20892, (301) 435-1171.

The meetings will be closed in accordance with the provisions set forth in sections 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. (Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 14, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-13166 Filed 5-23-96; 8:45 am]

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Substance Abuse and Mental Health Services Administration

Special Emphasis Panel II

Pursuant to Pub. L. 92-463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel II in June.

A summary of the meeting may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: (301) 443-4783.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual contract proposals. These discussions could reveal personal information concerning individuals associated with the proposals and confidential and financial information about an individual's proposal. The discussion may also reveal information about procurement activities exempt from disclosure by statute and trade secrets and commercial or financial information obtained from a person and privileged and confidential. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c) (3), (4), and (6) and 5 U.S.C. App. 2, section 10(d).

Committee Name: SAMHSA Special Emphasis Panel II.

Meeting Date: June 3, 1996.

Place: Parklawn Building—Conference Room "O", 5600 Fishers Lane, Rockville, Maryland 20852.

Closed: June 3, 1996, 10:30 a.m.-12:30 p.m.

Contact: Ferdinand W. Hui, Ph.D., Room 17-89, Parklawn Building, Telephone: (301) 443-9912 and FAX: (301) 443-3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: May 20, 1996.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 96-13103 Filed 5-23-96; 8:45 am]

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