

10. What methods are available to provide users with more access to device labeling?

11. Are there other issues with the labeling regulation or the labeling procedures used by CDRH that the agency should address?

12. Relating to FDA's medical device reporting system, what are the concerns if the agency would require manufacturers to submit periodic summary reports for common and anticipated adverse events that are listed in the device labeling, in lieu of individual incident reports. The agency's interest in requiring summary reporting for anticipated adverse events already listed in the labeling is to improve the signals received in the medical device reporting system and to reduce repeat reports of known problems when further agency action is unlikely. What adverse events should still be reported individually, even if the events are anticipated and listed in the labeling?

Interested persons who wish to participate may, on or before August 22, 1997, submit notice of participation to the Dockets Management Branch (address above). All notices of participation submitted should be identified with the docket number found in brackets in the heading of this document and should contain the name, address, telephone number, business affiliation of the person requesting to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation.

Individuals or groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. FDA will allocate the time available for the meeting among the persons who properly file a notice of appearance.

Persons who are unable to participate on the day of the meeting are encouraged to submit written comments to the Dockets Management Branch (address above). 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-20312 Filed 7-31-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; 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 National Institute of Dental Research Special Emphasis Panel (SEP) meeting:

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of R01s & R29 (97-43).

Date: August 12, 1997.

Time: 9:30 a.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

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

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.

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research)

Dated: July 29, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-20324 Filed 7-31-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Notice is hereby given of a meeting of the NIDCD Work Group on Peer Review on August 21-23, 1997 in Conference Room 10, Building 31, the National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892. The meeting will be held to discuss issues involving the initial review of grant applications and will be held from 3 to 5 p.m. on August 21, 8:30 a.m. to 5 p.m. on

August 22, and from 8:30 a.m. to 12 p.m. on August 23.

The entire meeting is open to the public. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Craig A. Jordan, Ph.D., Division of Extramural Activities, NIDCD, EPS Room 400C, Bethesda, MD 20892, 301-496-8693 in advance of the meeting.

Dated: July 29, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-20325 Filed 7-31-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting of National Advisory Environmental Health Sciences Council

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Environmental Health Sciences Council, September 15-16, 1997, Building 101 Conference Room, South Campus, Research Triangle Park, North Carolina.

This meeting will be open to the public from 9:00 a.m. to approximately 3:45 p.m. on September 15 for the report of the Director, NIEHS, and for discussion of the NIEHS budget, program policies and issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. and sec. 10(d) of Pub. L. 92-463, the meeting will be closed to the public from approximately 3:45 p.m. on September 15 to adjournment on September 16, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dr. Anne Sassaman, Director, Division of Extramural Research and Training,

and Executive Secretary, National Advisory Environmental Health Sciences Council, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709, (919) 541-7723, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: July 29, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-20326 Filed 7-31-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 National Institute on Drug Abuse (NIDA) Special Emphasis Panel meeting:

Purpose/Agenda: To evaluate and review contract proposals.

Name of Committee: NIDA Special Emphasis Panel.

Date: August 21, 1997.

Time: 9:00 a.m.

Place: Double Tree Inn Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mr. Lyle Furr, Contract Review Specialist, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10-42, Rockville, MD 20857, Telephone (301) 443-1644.

The meeting will be closed in accordance with provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The 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 personal privacy. (Catalog of Federal Domestic Assistance Program Numbers; 93.277, Drug Abuse Scientist Development, Research Scientist Development, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health.)

Dated: July 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-20327 Filed 7-31-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 meetings 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: August 5, 1997.

Time: 2 p.m.

Place: Parklawn, Room 9C-26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Sheri L. Schwartzback, Parklawn, Room 9C-26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443-4843.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: August 14, 1997.

Time: 9:30 a.m.

Place: Wash. National Airport Hilton, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Emeline M. Otey, Parklawn, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443-4868.

The meetings 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.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle. (Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: July 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-20328 Filed 7-31-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council and its subcommittee. These meetings will be open to the public as indicated below. Attendance by the public will be limited to space available.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters of committee members, and other information pertaining to the meetings can be obtained from the Executive Secretary. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary.

Name of Committee: The Planning Subcommittee of the National Advisory Neurological Disorders and Stroke Council.

Date: September 10, 1997.

Place: National Institutes of Health, Building 1, Wilson Hall, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: 1:30 p.m.-recess.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: September 11-12, 1997.

Place: National Institutes of Health, Building 1, Wilson Hall; 8A28, 9000 Rockville Pike, Bethesda, MD 20892.

Open: September 11, 8:30 a.m.-recess.

Agenda: A report by the Director, NINDS; a report by the Director, Division of Extramural Activities, NINDS; a scientific presentation by an NINDS grantee; and discussion of Institute policies.

Closed: September 12, 8:30 a.m.-adjournment.

Executive Secretary: Constance W. Atwell, Ph.D., Director, Division of Extramural Activities, NINDS, National Institute of Health, Bethesda, MD 20892, Telephone: (301) 496-9248.

(Catalog of Federal Domestic Assistance Program No. 93.853, Clinical Research