

act and pediatric exclusivity. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

II. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for proposed pediatric studies is already covered by the collection of information on investigational new drug application regulations (21 CFR part 312) submitted to the Office of Management and Budget (OMB) for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection and assigned OMB control number 0910–0014. The approval expires on December 31, 1999.

III. Electronic Access

Copies of this guidance for industry are available on the Internet at “http://www.fda.gov/cder/guidance/index.htm” and at “http://www.fda.gov/cber/guidelines.htm”.

Dated: September 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–26224 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995.

Proposed Project: Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915–0044)—Revision

The HPSL Program provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, an associate degree, a baccalaureate degree, or a graduate degree in nursing. Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The deferment form (HRSA form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR—HRSA form 501) provides the Federal Government with information from participating and non-participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The estimate of burden is as follows:

Form No.	Number of respondents	Response per response	Total annual respondents	Hours per respondents	Total burden hours
Defer—HRSA—519	10,358	1	10,358	¹ 10	1,726
AOR—HRSA—501	1,302	1	1,302	² 4	5,208
Total Burden	11,660	11,660	6,934

¹ Minutes.

² Hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 30, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–26225 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G—Education.

Date: November 3–5, 1999.

Agenda: 1 p.m. to 12 p.m.

Place: Georgetown Holiday Inn, 2101 Wisconsin Ave, NW., Washington, DC 20007.

Contact Person: Harvey P. Stein, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Rm. 611B, Rockville, MD 20892, 301–496–7481.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 30, 1999.

Nancy Middendorf,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99-26238 Filed 10-7-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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.

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

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, U24 Cooperative Agreement.

Date: October 7, 1999.

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Rockledge Center II, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Terry Bishop, Scientific Review Administrator, Review Branch, NIH, NHLBI, DEA, Rockledge Center II, 6701 Rockledge Drive, Suite 7210, Bethesda, MD 20892-7924, (301) 435-0303.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 30, 1999.

Nancy Middendorf,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99-26237 Filed 10-7-99; 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.

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

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

Date: November 1, 1999.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Contact Person: Robert H. Stretch, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6150, MSC 9608, Bethesda, MD 20892-9608, 301-443-4728.

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

Date: November 12, 1999.

Time: 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jean G. Noronha, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892-9609, 301-443-6470.

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

Date: November 15, 1999.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: River Inn, 924 25th Street, NW, Washington, DC 20037.

Contact Person: Russell E. Martenson, Scientific Review Administrator, Division of

Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6138, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861.

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

Date: November 23, 1999.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Russell E. Martenson, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6138, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861.

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

Date: November 30, 1999.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Contact Person: Robert H. Stretch, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6150, MSC 9608, Bethesda, MD 20892-9606, 301-443-4728.

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

Date: December 2, 1999.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Russell E. Martenson, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6138, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated October 1, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99-26233 Filed 10-7-99; 8:45 am]

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