

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.35	13	1	13	10	130

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that 13 such petitions are received by the agency annually, with each requiring approximately 10 hours of preparation time.

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-266 Filed 1-4-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 19, 2001, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact: Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a cervical interbody fusion system.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the

committee. Written submissions may be made to the contact person by January 12, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and an additional 30 minutes of open public hearing will be scheduled prior to the end of committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 12, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-267 Filed 1-4-01; 8:45 am]

BILLING CODE: 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: President's Cancer Panel.

Date: February 1-2, 2001.

Time: 9 am to 4 pm.

Agenda: Improving Cancer Care for All: Real People—Real Problems.

Place: USC/Norris Comprehensive Cancer Center, University of Southern California, 1441 Eastlake Avenue, Los Angeles, CA 90033.

Contact Person: Maureen O. Wilson, Executive Secretary, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 4A48, Bethesda, MD 20892, 301/496-1148.

(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: December 27, 2000.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-334 Filed 1-4-01; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 Eye Institute Special Emphasis Panel.

Date: January 4, 2001.

Time: 9 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: 6120 Executive Blvd. Suite 350, Rockville, MD 20892.

Contact Person: Andrew P Mariani, PhD, Chief, Scientific Review Branch, 6120 Executive Blvd, Suite 350, Rockville, MD 20892, 301/496-5561.

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. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 22, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-336 Filed 1-4-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of 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 open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: Microbiology and Infectious Diseases Research Committee.

Date: February 7-9, 2001.

Open: February 7, 2001, 9 a.m. to 10 a.m..

Agenda: Reports from various Institute staff.

Place: Holiday Inn Georgetown, Mirage II, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Closed: February 7, 2001, 10 a.m. to adjournment on February 9, 2001.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, Mirage II, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Gary S. Madonna, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2217, 6700-B Rockledge Drive, MSC 7610, Bethesda, MD 20892-7610, 301-496-2550.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,

Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 22, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-335 Filed 1-4-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Medicine; Notice of 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 open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 journals as potential titles to be indexed by the National Library of Medicine and the discussions could disclose confidential trade secrets of commercial property such as patentable material, and personal information concerning individuals associated with the journals as potential titles to be indexed by the National Library of Medicine, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Literature Selection Technical Review Committee.

Date: February 8-9, 2001.

Open: February 8, 2001, 9am to 11am.

Agenda: Administrative Reports and Program Developments.

Place: National Library of Medicine, Board Room Bldg 38, 2E-09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 8, 2001, 11 am to 5 pm.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Board Room Bldg 38, 2E-09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 9, 2001, 8:30 am to 2 pm.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Board Room Bldg 38, 2E-09, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Sheldon Kotzin, BA, Chief, Bibliographic Services Division, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Bldg 38A/Room 4N419, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 27, 2000.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-333 Filed 1-4-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: This notice amends the NIH Guidelines to set forth NIH's policy on in utero gene transfer clinical research. At the present time, there is insufficient basic and preclinical data to justify the conduct of in utero gene transfer clinical research. Before any in utero gene transfer clinical trial could proceed, significant additional preclinical and relevant clinical studies addressing biodistribution, toxicity, and efficiency of vector transduction would be required, as would further deliberations of the ethical issues associated with this research. As new knowledge evolves from basic, preclinical, and relevant clinical research and as the ethical issues are addressed, the NIH would consider in utero gene transfer clinical protocols for review by the Recombinant DNA Advisory Committee (RAC).

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Biotechnology Activities (OBA), National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, Phone 301-496-9838, FAX 301-496-9839. The OBA Web site is located at <http://www.nih.gov/od/oba/>.

Background Information

In September 1998, the NIH RAC discussed two preliminary proposals for human in utero gene transfer and