

effectiveness, and reliability, and display in the labeling and advertising of certain warnings. Section 814.84 specifies the contents of periodic reports. Section 814.82 requires the maintenance of records to trace patients and the organizing and indexing of records into identifiable files to enable FDA to determine whether there is reasonable assurance of the device's continued safety and effectiveness. The applicant determines what records should be maintained during product development to document and/or

substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required to be maintained as conditions of approval to ensure the device's continuing safety and effectiveness.

Respondents to this information collection are persons filing an application with the Secretary of Health

and Human Services for approval of a Class III medical device. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments).

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 814.15, 814.20, and 814.37 | 545 | 1 | 545 | 837.28 | 456,320 |
| 814.39 | 545 | 1 | 545 | 73.15 | 39,865 |
| 814.82 | 545 | 1 | 545 | 9.14 | 4,983 |
| 814.84 | 545 | 1 | 545 | 18.29 | 9,966 |
| Total Hours | | | | | 511,134 |

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

ESTIMATED ANNUAL RECORDKEEPING BURDEN

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|-------------------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 814.82(a)(5) and (a)(6) | 567 | 1 | 567 | 16.7 | 9,469 |
| Total | | | | | 9,469 |

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

Dated: December 31, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-291 Filed 1-6-97; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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:

Committee Name: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel (Telephone Conference Call).

Date: January 6, 1997.

Place: Natcher Building, Room 6AS-25F, National Institutes of Health, 45, Center Drive, Bethesda, Maryland 20892-6600.

Contact Person: Lakshmanan Sankaran, Ph. D., Scientific Review Administrator, Natcher Building, Room 6AS-25F, National Institutes of Health, 45 Center Drive, Bethesda, Maryland 20892-6600; Phone: 301-594-7799.

Agenda/Purpose: To review and evaluate a research grant application.

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.

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. Application 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. 93.847-849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health.)

Dated: December 26, 1996.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 97-319 Filed 1-2-97; 4:43 pm]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming; Notice of amendment to Approved Tribal-State Compact

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100-497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved Amendment II to the Tribal-State Compact for Regulation of Class III Gaming Between The Klamath Tribes and the State of Oregon, which was executed on November 13, 1996.

DATES: This action is effective January 7, 1997.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240 (202) 219-4068.

Dated: December 26, 1996.
 Elizabeth L. Homer,
Assistant Secretary—Indian Affairs.
 [FR Doc. 97-245 Filed 1-6-97; 8:45 am]
 BILLING CODE 4310-02-P

Indian Gaming; Notice of Approved Second Amendment to Tribal-State Compact

AGENCY: Bureau of Indian Affairs, Interior.
SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100-497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gaming on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Second Amendment to the Tribal-State Gaming Compact Between the Swinomish Indian Tribal Community and the State of Washington executed on October 4, 1996.

DATES: This action is effective January 7, 1997.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240 (202) 219-4068.

Dated: December 26, 1996.
 Elizabeth L. Homer,
Assistant Secretary—Indian Affairs.
 [FR Doc. 97-244 Filed 1-6-97; 8:45 am]
 BILLING CODE 4310-02-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (97-001)]

NASA Advisory Council (NAC), Space Science Advisory Committee (SScAC), Solar System Exploration Advisory Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Space Science Advisory Committee, Solar System Exploration Advisory Subcommittee.

DATES: Wednesday, January 15, 1997, 8:30 a.m. to 5:00 p.m.; Thursday, January 16, 1997, 8:30 a.m. to 5:00 p.m.;

and Friday, January 17, 1997, 8:30 a.m., 4:00 p.m.

ADDRESSES: National Aeronautics and Space Administration, MIC Room 6H46, 300 E Street, SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Jurgen Rahe, Code SA, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358-2150.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The agenda for the meeting is as follows:

- Office of Space Science Activities
- Board of Directors Overview
- Research Program Management Overview
- Advanced Technology and Mission Studies Overview
- Mission and Payload Development, Overview
- Roadmap to the Solar System
- Future Activities

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: January 2, 1997.
 Leslie M. Nolan,
*Advisory Committee Management Officer,
 National Aeronautics and Space Administration.*
 [FR Doc. 97-289 Filed 1-6-97; 8:45 am]
 BILLING CODE 7510-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Advanced Scientific Computing; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Advanced Scientific Computing (#1185)
Date and Time: January 24, 1997, 8:30 am to 5:00 pm.

Place: National Science Foundation, 4201 Wilson Boulevard, Suite 1150, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. John Van Rosendale, Program Director, New Technologies Program, Suite 1122, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306-1962.

Purpose of Meeting: To provide recommendations and advice concerning proposals submitted NSF for financial support.

Agenda: Panel review of CISE Postdoctoral Research Associates in Computational Science and Engineering proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552(b)(4) and (6) of the Government in the Sunshine Act.

Dated: January 2, 1997.
 M. Rebecca Winkler,
Committee Management Officer.
 [FR Doc. 97-273 Filed 1-6-97; 8:45 am]
 BILLING CODE 7555-01-M

Special Emphasis Panel in Astronomical Sciences (1186); Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces that the Special Emphasis Panel in Astronomical Sciences (1186) will be holding panel meetings for the purpose of reviewing proposals submitted to the Career Program in the area of Astronomical Sciences. In order to review the large volume of proposals, panel meetings will be held on January 30-31, 1997, (2). All meetings will be closed to the public and will be held at the National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia, from 8:30 AM to 5:00 PM each day.

Contact Person: Dr. James P. Wright, Program Director, Education, Human Resources, and Special Programs, Division of Astronomical Sciences, National Science Foundation, Room 1030, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306-1819.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 USC 552(c)(4) and (6) of the Government in the Sunshine Act.

Dated: January 2, 1997.
 M. Rebecca Winkler,
Committee Management Officer.
 [FR Doc. 97-271 Filed 1-6-97; 8:45 am]
 BILLING CODE 7555-01-M

Special Emphasis Panel in Bioengineering and Environmental System; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting: