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.