The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee at its meeting in July reaffirmed the ranges it had established in January for growth of M2 and M3 of 1 to 5 percent and 2 to 6 percent respectively, measured from the fourth quarter of 1995 to the fourth quarter of 1996. The monitoring range for growth of total domestic nonfinancial debt was maintained at 3 to 7 percent for the year. For 1997 the Committee agreed on a tentative basis to set the same ranges as in 1996 for growth of the monetary aggregages and debt, measured from the fourth quarter of 1996 to the fourth quarter of 1997. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks to maintain the existing degree of pressure on reserve positions. In the context of the Committee's long-run objectives for price stability and sustainable economic growth, and giving careful consideration to economic, financial, and monetary developments, somewhat greater reserve restraint would or slightly lesser reserve restraint might be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with moderate growth in M2 and relatively strong expansion in M3 over coming months.

By order of the Federal Open Market Committee, December 27, 1996.

Donald L. Kohn,

Secretary, Federal Open Market Committee.

[FR Doc. 97-250 Filed 1-6-97; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0491]

Agency Information Collection Activities: Proposed Collection; Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for premarket approval applications (PMA's) that are submitted under part 814 (21 CFR part 814).

DATES: Submit written comments on the collection of information requirements by March 10, 1997.

ADDRESSES: Submit written comments on the collection of information requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Approval of Medical Devices—Part 814 (OMB Control Number 0910–0231—Reinstatement)

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth requirements for premarket approval of certain medical devices. Under section 515 of the act, an application must contain several pieces of information, including: Full reports of all information concerning investigations showing whether the device is safe and effective; a statement of components; a full description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device; and labeling specimens. The implementing regulations, contained in part 814, further specify the contents of a PMA for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA. The purpose of these regulations is to establish an efficient and thorough procedure for FDA's review of PMA's for class III (premarket approval) medical devices, in order to facilitate the approval of PMA's for devices that have been shown to be safe and effective and otherwise meet the statutory criteria for approval and to ensure the disapproval of PMA's for devices that have not been show to be safe and effective and that do not otherwise meet the statutory criteria for approval.

Under § 814.15, an applicant may submit in support of a PMA studies from research conducted outside the United States, but an applicant must explain in detail any differences between standards used in a study to support the PMA's and those standards found in the Declaration of Helsinki. Section 814.20 provides a list of information required in the PMA, including: A summary of information in the application, a complete description of the device, technical and scientific information, and copies of proposed labeling. Section 814.37 provides requirements for an applicant who seeks to amend a pending PMA. Under § 814.39, an applicant must submit a supplement to the PMA before making a change affecting the safety or effectiveness of the device. Section 814.82 sets forth postapproval requirements FDA may propose, including periodic reporting on safety,

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.