SUPPLEMENTARY INFORMATION: On April 27, 1995, Sulzer Orthopedics®, Inc., Austin, TX 78717, submitted to CDRH an application for premarket approval of the Natural Knee® and Natural Knee® II with CSTi™. These devices are biologically fixed total knee prostheses and are indicated for uncemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease or Inflammatory Joint Disease.

On June 12, 1995, the Orthopedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On March 21, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDR

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 30, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 5, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–16968 Filed 6–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–462 A/B]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Adverse Action Extract 42 CFR 493.1840; *Form No.:* HCFA–462 A/B; *Use:* This form is used by HCFA surveyors (State health Department surveyors and other HCFA agents) to record which types of adverse actions are imposed against laboratories. The form will also serve to track dates of the imposition of adverse actions, dates on which a laboratory corrects deficiencies, and all appeals activity. *Frequency:* On occasion and biennially; *Affected Public:* Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 2,500; *Total Annual Responses:* 2,500; *Total Annual Hours:* 5,625

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, *Attention:* Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 10, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–16984 Filed 6–27–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under

the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: SPRANS/CISS Uniform Data Collection Instruments (OMB No. 0915–0169)—Extension and Revision—The Health Resources and Services Administration (HRSA) proposes to revise and reformat the Maternal and Child Health Special Projects of National and Regional Significance (SPRANS) and Community Integrated Service Systems (CISS) Uniform Data Collection Instruments. These revised instruments will be used to include information from grantees to comply with the legislative mandate for an annual report to Congress, and to include data for meeting the requirements of the Government Performance and Results Act (GPRA).

The SPRANS/CISS Programs complement and improve the MCH Block grants to the 50 states and 9 territories under Title V of the Social Security Act. Approximately 600 grants are awarded annually in the SPRANS/CISS programs, usually to state and local health departments, universities and other institutions of higher learning, and a smaller number of non-profit and for-profit organizations or associations. There are four separate SPRANS/CISS Uniform Data Collection Instruments, reflecting variations in the four basic types of SPRANS/CISS grantees and their unique data needs: (1) Training, (2) Research, (3) Data, and (4) Other Discretionary Programs.

The revisions to these data collection instruments are designed to ensure the collection of data needed by program managers to prepare the mandated annual report to Congress, and may be designed to ensure the collection of data required by GPRA without the introduction of additional collection instruments. We estimate that the burden hours will be decreased by more than 10%, due to further improvements to the instruments based on lessons learned from the initial use of the form, as well as improved technology that will be used to collect the data. Estimates of burden to complete the Uniform Data Collection Instruments are as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Training	150	1	1.75	262.5
Research	50	1	1.75	87.5
Data	30	1	1.75	52.5
Other Discretionary Programs	350	1	1.75	612.5
Total	580	1	1.75	1,015

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD, 20857. Written comments should be received within 60 days of this Notice.

Dated: June 24, 1997.

James J. Corrigan,

Acting Associate Administrator for Management and Program Support.

[FR Doc. 97–17063 Filed 6–27–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Cancellation of Meeting

Notice is hereby given of the cancellation of the meeting of the National Institutes of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, the Developing Kidney in Health and Disease, June 29–July 1, 1997, Albert Einstein College of Medicine, 1300 Morris Park Avenue, New York, which was published in the **Federal Register** on May 27, (62 FR 2873).

The meeting was canceled due to the withdrawal of the application for review.

Dated: June 24, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–17194 Filed 6–27–97; 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 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 of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: to review and evaluate grant applications.

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

Date: June 27, 1997.

Time: 1 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Salvador H. Cuellar, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–4868.

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. Applications 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.

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

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: June 25, 1997.

LaVerne Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–17195 Filed 6–27–97; 8:45 am]

BILLING CODE 4140–01–M