

person before August 9, 1997, 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.

Closed committee deliberations: On September 15, 1997, from 10 a.m. to 10:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will present trade secret and/or confidential information regarding pending and future submissions.

FDA regrets that it was unable to publish this notice 15 days prior to the September 15 and 16, 1997, General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: August 19, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-255]

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:* Municipal Health Services Cost Report Form, and supporting regulations 42 CFR 405.371; *Form No.:* HCFA-255; *Use:* The Municipal Health Services Program (MHSP) Cost Report (HCFA-255) is used by the participating MHSP clinics to report costs for health care services rendered to Medicare beneficiaries. It is also used to gather data to properly evaluate the MHSP demonstration. This form has been used since 1979. *Frequency:* Annually; *Affected Public:* Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 14; *Total Annual Responses:* 14; *Total Annual Hours:* 476.

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, DC 20503.

Dated: August 8, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office for Protection From Research Risks; Proposed Collection; Comment Request; Protection of Human Subjects: Assurance Identification/Certification/Declaration

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office for Protection from Research Risks (OPRR), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Protection of Human Subjects: Assurance Identification/Certification/Declaration. *Type of Information Collection Request:* Extension. *OMB Control Number:* 0925-0418. *Expiration Date:* 12/31/97. *Need and Use of Information Collection:* The Federal Policy for the Protection of Human Subjects was promulgated on June 18, 1991 (56 FR 28003) and requires applicant and awardee institutions receiving Federal funds to initiate procedures to report, disclose and keep required records for the protection of human subjects of research. Optional Form 310, Protection of Human Subjects: Assurance Identification/Certification/Declaration is necessary for the implementation and administration of the reporting and recordkeeping requirements set forth in the Federal Policy. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; Business or other for-profit; Not for-profit institutions; Federal Government; State, local or tribal government. *Type of Respondents:* Researchers. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,831. *Estimated Number of Responses per Respondent:* 56.8. *Average burden hours per response:* 0.755; and *Estimated Total Annual Burden Hours Requested:* 164,428. The annualized cost to respondents is estimated at: \$2,096. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the