

*Place:* Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 705A, Washington, DC 20201.

*Status:* Open.

*Purpose:* The agenda for Tuesday, January 27th, will be devoted to final reports on standards for five domains that were prepared as part of the Consolidated Health Informatics Initiative (CHI) and a related letter on CHI recommendations to the Secretary will be finalized. The afternoon will focus on issues related to the implementation of the HIPAA Security Rule.

The morning of the second day will include an update on implementation of HIPAA transactions and code sets provisions; the development of a draft letter to the Secretary concerning the Claims Attachment Standard; and a session on dental data standards issues. The afternoon will be devoted to Subcommittee planning of future activities around E-prescriptions.

**FOR FURTHER INFORMATION**

*CONTACT:* Substantive program information as well as summaries of meetings and a roster of Committee members may be obtained from Maria Friedman, Health Insurance Specialist, Security and Standards Group, Centers for Medical and Medicaid Services, MS: C5-24-04, 7500 Security Boulevard, Baltimore, MD 21244-1850, telephone: (410) 786-6333 or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone: (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/> where an agenda for the meeting will be posted when available. Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: December 24, 2003.

**James Scanlon,**

*Acting Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 04-396 Filed 1-8-04; 8:45 am]

**BILLING CODE 4151-05-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration on Aging**

**Agency Information Collection Activities; Proposed Collection; Comment Request; AoA Nutrition and Physical Activity Campaign**

**AGENCY:** Administration on Aging, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Aging (AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies

are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to organizations that wish to enroll as a partner with AoA in a campaign to create awareness and make nutrition and physical activity programs available to older Americans. The requested information includes providing general information about the entity, its programs, and counts of populations served.

**DATES:** Submit written or electronic comments on the collection of information by March 9, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to:

*Kathleen.Loughrey@aoa.gov.*

Submit written comments on the collection of information to Administration on Aging, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:**

Kathleen Loughrey, U.S. Department of Health and Human Services, Administration on Aging, Washington, DC 20201.

**SUPPLEMENTARY INFORMATION:** Under 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 request 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 extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA'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.

**Describe Collection of Information**

AoA estimates the burden of this collection of information as follows: AoA estimates a total of no more than 500 hours will be required to collect this information. This estimate is based on these assumptions: AoA estimates that 2,000 organizations will complete an entry form to become a campaign partner. Completion of each entry form will require a total of 15 minutes per organization including five minutes to answer questions, five minutes to insert a program description, and five minutes to look up data from existing program records.

Dated: January 2, 2004.

**Josefina G. Carbonell,**

*Assistant Secretary for Aging.*

[FR Doc. 04-471 Filed 1-8-04; 8:45 am]

**BILLING CODE 4154-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0311]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 10, 2003 (68

FR 58690), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0508. The approval expires on December 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 31, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-394 Filed 1-8-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; Comment Request, Determinants of Male and Female Fecundity and Fertility

**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 National Institute of Child Health and Human Development (NICHD), 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:* Determinants of Male and Female Fecundity and Fertility. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will assess the relation between select environmental factors and human fecundity and fertility. This research proposes to recruit 960 couples who are interested in becoming pregnant and willing to participate in a longitudinal study. Fecundity will be measured by the time required for the couples to achieve pregnancy, while fertility will be measured by the ability of couples to have a live born infant. Couples who are unable to conceive within 12 months of trying or who experience a miscarriage also will be identified and considered to have fecundity-related impairments. The study's primary environmental exposures include: organochlorine pesticides and polychlorinated biphenyls; metals; fluorinated

compounds; phytoestrogens; and phthalates. A growing body of literature suggests these compounds may exert effects on human reproduction and development; however, definitive data are lacking serving as the impetus for this study. Couples will participate in a 20-30 minute baseline interview and be instructed in the use of home fertility monitors and pregnancy kits for counting the time required for pregnancy and detecting pregnancy. Blood and urine samples will be collected at baseline from both partners of the couple for measurement of the environmental exposures. Two semen samples from male partners and two saliva samples from female partners also will be requested. Semen samples will be used to assess male fecundity as measured primarily by sperm concentration and morphology. Saliva samples will be used for the measurement of cortisol levels as a marker of stress among female partners so that the relation between environmental factors, stress and human reproduction can be assessed. The findings will provide valuable information regarding the effect of environmental contaminants on sensitive markers of human reproduction and development, filling critical data gaps. Moreover, these environmental exposures will be analyzed in the context of other lifestyle exposures, consistent with the manner in which human beings are exposed. *Frequency of Response:* Following the baseline interview, couples will each complete a five-minute daily diary on select lifestyle factors. Women will perform daily fertility testing and pregnancy testing at day of expected menses using a dipstick test in urine. Each test will require approximately five minutes for completion. This testing and diary reporting is required only up to the time women become pregnant, which on average should be in 2-3 months. Men will provide two semen samples, a month apart, requiring approximately 20 minutes for each collection, and women will collect two saliva samples, a month apart, requiring approximately five minutes. Participating couples will be given a choice to submit their information by mail or to send it electronically to the Data Coordinating Center. This option will be available throughout data collection in the event couples change their minds about how they would like to submit information. Biospecimens will be collected by study participants and research nurses, where appropriate, and forwarded in prepaid delivery packages to the study's laboratories.

*Affected Public:* Individuals from participating communities. *Type of Respondents:* Men and women aged 18-40 years. *Estimated Number of Respondents:* 1,920. *Estimated Number of Response Sets Per Respondent:* 6 per women and 3 per men over approximately two years. *Average Burden Hours Per Response:* .1947 for women and .31975 for men. *Estimated Total Annual Burden Hours Requested:* 3,183 for women and 1,706 for men. There is no cost to respondents. 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 following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Germaine Buck, Chief, Epidemiology Branch, DESPR, NICHD, NIH, 6100 Executive Blvd., Room 7B03, Rockville, Maryland 20852, or call non-toll-free number (301) 496-6155 or e-mail your request, including your address to: [gb156i@nih.gov](mailto:gb156i@nih.gov).

*Comments Due Date:* Comments regarding this information are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: December 30, 2003.

**Ayesha Giles,**

*Project Clearance Liaison, NICHD, National Institutes of Health.*

[FR Doc. 04-453 Filed 1-8-04; 8:45 am]

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