

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-06-06BN]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

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. Written comments should be received within 60 days of this notice.

**Proposed Project**

Conduct a Chronic Fatigue Syndrome Registry Pilot Test (Bibb County, Georgia)—New—National Center for Infectious Diseases (NCID) Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

CDC is tasked with establishing a registry of chronic fatigue syndrome (CFS) and other fatiguing illnesses. The objective of the registry is to identify persons with unexplained fatiguing illnesses, including CFS, who access the healthcare system because of their symptoms. Patients will be between the ages of 12 and 59, inclusive.

Specific aims of the registry are: (1) Identify and enroll patients with CFS and other unexplained fatiguing illnesses who are receiving medical and ancillary medical care and describe their epidemiologic and clinical characteristics; (2) follow CFS patients and patients with other fatiguing illnesses over time to characterize the natural history of CFS and other unexplained fatiguing illnesses; (3) assess and monitor health care providers' knowledge, attitudes, and beliefs concerning CFS; (4) and to identify well-characterized CFS patients for clinical studies and intervention trials. These specific aims require inclusion of subjects in early stages of CFS (*i.e.*, ill less than one year duration) who can be followed longitudinally to

assess changes in their CFS symptoms. Data on persons with CFS in the general population has been collected in a separate study and is not an objective of this Registry.

In order to determine the most effective and cost-efficient design for achieving the objective and specific aims, CDC will conduct a pilot test of the Registry of CFS and other fatiguing illnesses in Bibb County, Georgia. The CFS Registry Pilot Test will assess two Registry designs for efficacy and efficiency in identifying adult and adolescent subjects with CFS who are receiving medical and ancillary medical care. Specifically, the CFS Registry Pilot Test will evaluate surveillance of patients with CFS identified through physician practices and a surveillance of CFS patients identified by physicians and other health care providers.

The proposed study will begin when a provider refers a patient to the registry. Patients who consent to be contacted for the registry will be asked to complete a detailed telephone interview that screens for medical and psychiatric eligibility. Eligible subjects will be invited to have a clinical evaluation that comprises a physical examination; collection of blood, urine, and saliva specimens; a mental health interview; and self-administered questionnaires.

There is no cost to respondents other than their time. Patients who are clinically evaluated will be reimbursed for their time and effort. The total annualized burden hours are 2,557.

*Estimate of Annualized Burden Hours*

Respondent	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (hours)
Referring Providers .....	400	2	5/60	67
Patient consent to be contacted .....	677	1	10/60	113
Patient Telephone Interview .....	541	1	30/60	271
Patient Clinical Evaluation .....	234	1	540/60	2,106
<b>Total Burden .....</b>	.....	.....	.....	<b>2,557</b>

Dated: August 15, 2006.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* TANF Labor Market Survey.

*OMB No.:* New Collection.

*Description:* Understanding the motivations, hiring practices, and work place policies of employers—the

demand side of the labor market—can provide considerable information to policy makers interested in promoting work and advancement among welfare recipients and other less-skilled workers. This project will add to our knowledge in this area by surveying employers in the TANF/low-wage labor market. We will survey a national sample of employers, focusing on industry sectors with the most jobs in the low-wage labor market, the employers most relevant for the majority

of current and recent TANF recipients. The survey will gather information from employers on their attitudes, practices, and policies toward TANF recipient and other low-skill hires, including information on worker advancement, the use of work force intermediaries in hiring, and the role that child care plays in worker retention. The survey will allow for comparisons of employers in

urban-core areas, suburbs, and exurbs/ rural areas. It will also measure employment outcomes for TANF recipients and other low-skilled workers, allowing us to draw connections between employer practices and employee outcomes. In short, this national survey of employers in the low-wage labor market can provide key information on what employer practices

and policies are and how they are associated with workplace success for welfare recipients and other less-skilled workers.

*Respondents:* A nationally representative sample of business establishments having 4 or more workers.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF Labor Market Survey .....	1,300	1	0.33	429

#### *Estimated Total Annual Burden Hours: 429.*

*Additional Information:* copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: [Katherine.T.Astrich@omb.eop.gov](mailto:Katherine.T.Astrich@omb.eop.gov).

Dated: August 15, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0320]

#### Molecular Methods in Immuno-hematology; Public Workshop

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Molecular Methods in Immuno-hematology." The purpose of the public workshop is to gather and review current information on scientific developments that might enhance immuno-hematologic testing of blood donor or patient blood samples as part of pre-transfusion compatibility testing, or in determination and management of feto-maternal blood group incompatibilities.

*Date and Time:* The public workshop will be held on September 25, 2006, from 8:30 a.m. to 5 p.m., and September 26, 2006, from 8:30 a.m. to 2 p.m.

*Location:* The public workshop will be held at the Lister Hill Center Auditorium, bldg. 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

*Contact Person:* Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: [rhonda.dawson@fda.hhs.gov](mailto:rhonda.dawson@fda.hhs.gov).

*Registration:* Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by September 15, 2006. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8:00 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The public workshop will feature presentations by national and international experts from government,

academic institutions, and industry. The main goal of the workshop is to determine potential applications of molecular methods to improve safety in transfusion medicine by overcoming current limitations in the field of immuno-hematology, namely, the lack of reagent grade antibodies, both polyclonal and monoclonal; variability of reactivity of monoclonal antibodies as compared to polyclonal antibodies; and inherent limitations in the hemagglutination test. Topics to be discussed include the following: (1) Use of molecular methods in platelet and leukocyte typing, (2) use of phage display technology in place of routine hemagglutination tests, (3) potential advantages of using molecular methods in donor screening and patient typing, (4) use of molecular methods to resolve unusual serologic findings, (5) potential use of molecular methods in the manufacture of immuno-hematology reagents, and (6) current limitations in the use of molecular methods.

*Transcripts:* Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: August 14, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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