

Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### *Background and Brief Description*

CDC currently supports the National Program of Cancer Registries (NPCR), a group of central cancer registries in 45 states, the District of Columbia, and 2 territories. The central cancer registries are data systems that collect, manage, and analyze data about cancer cases and cancer deaths. NPCR-funded central cancer registries submit population-based cancer incidence data to CDC on an annual basis (OMB No. 0920-0469, exp. 1/31/2010). In addition, NPCR-funded registries submit program and performance indicator information to CDC on a semi-annual schedule (OMB No. 0920-0706, exp. 12/31/2011). CDC uses the performance indicators to evaluate the registries' use of funds, their progress toward meeting objectives, and their infrastructure and operational attributes.

Central cancer registries report that they are chronically understaffed, and many registries are concerned about the impact of staff shortages on data quality standards. Staffing patterns are known to vary widely from registry to registry, and registries differ greatly in the number of incidence cases that they process as well as their use of information technology. Cancer registries have asked for clear staffing guidelines based on registry characteristics such as size (i.e., number of new cases annually), degree of automation, and registry-specific reporting procedures.

CDC proposes to conduct a one-time Workload Management Survey (WLM) in 2009-2010 to inform the development of staffing guidelines for central cancer registries. The WLM survey questions do not duplicate the program and performance indicator information reported to CDC on a routine basis. Respondents will be cancer registrars in the NPCR-funded

central cancer registries in 45 states and the District of Columbia. Cancer registrars at each registry will maintain a paper-based Work Activities Journal for a one-week period. At the end of the week, the registry manager will consolidate the individual journal worksheets to prepare an aggregate Workload Management Survey for the registry, which will be submitted to CDC electronically.

Results of the WLM survey will enable CDC to assess the workforce necessary for meeting data reporting requirements and to estimate the impact of planned changes to surveillance data reporting. Finally, CDC will develop specific guidance so that cancer registry managers can more effectively measure workload, evaluate the need for staff and staff credentials, and advocate for adequate staffing.

Participation in the survey is voluntary. There are no costs to respondents other than their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents   | Form name                        | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|-----------------------|----------------------------------|-----------------------|------------------------------------|--|-------------------------|
| NPCR Registries ..... | Workload Management Survey ..... | 46                    | 1                                  | 4                                      | 184                     |
|                       | Work Activities Journal .....    | 368                   | 1                                  | 2                                      | 736                     |
| Total .....           | .....                            | .....                 | .....                              | .....                                  | 920                     |

Dated: June 1, 2009.

**Maryam I. Daneshvar,**

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

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

[60Day-09-09BU]

#### 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 or send comments to Maryam I. Daneshvar, CDC Acting 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

National Adult Tobacco Survey (NATS)—New—National Center for Chronic Disease Prevention and Health

Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### *Background and Brief Description*

Despite the high level of public knowledge about the adverse effects of smoking, tobacco use remains the leading preventable cause of disease and death in the United States. Tobacco use results in approximately 440,000 deaths annually, including approximately 38,000 deaths from secondhand smoke exposure. Adults who smoke contribute to \$92 billion annually in lost worker productivity, and die an average of 14 years earlier than nonsmokers. Although the prevalence of current smoking among adults decreased significantly from 1998 to 2007 in 44 states, the District of Columbia, and Puerto Rico, only one state and one territory have met Healthy People 2010 targets for reducing adult smoking prevalence to 12%, and six states have shown no substantial changes in prevalence after controlling for age, sex, and race/ethnicity.

The National Tobacco Control Program (NTCP) was established by CDC to help reduce tobacco-related

disease, disability, and death. The NTCP's four goal areas are: (1) The prevention of initiation of tobacco use among young people, (2) the elimination of nonsmokers' exposure to secondhand smoke, (3) the promotion of quitting among adults and young people, and (4) the elimination of tobacco-related disparities.

CDC proposes to conduct the National Adult Tobacco Survey (NATS) in order to collect essential information on key indicators of the effectiveness for the NTCP. The NATS will be a one-time, stratified, random-digit dialed telephone survey of non-institutionalized adults 18 years of age and older. In order to

yield results that are representative and comparable at both national and state levels, information will be collected from 3,000 respondents per state and the District of Columbia. In addition, a total of approximately 3,000 interviews will be conducted specifically from a national sample of cell phone users in an attempt to include the growing population of households that exclusively use cell phones and would be missed in a survey relying only on land-lines.

Information collected through the NATS will be used to: (1) Generate state-level estimates of tobacco use for males and females, (2) generate state-

level estimates of tobacco use for minority groups comprising a major component of a given state's population, (3) develop estimates of tobacco use at the national level by gender and race/ethnicity, and (4) support the evaluation of comprehensive state-based Tobacco Control Programs using key outcome indicators at the state and national levels. Study results will have significant implications for the development of policies and programs aimed at preventing or reducing tobacco use. There are no costs to respondents except their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent            | Form name                           | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|-------------------------------|-------------------------------------|-----------------------|------------------------------------|--|-------------------------|
| Adults ages 18 or older ..... | National Adult Tobacco Survey ..... | 156,000               | 1                                  | 22/60                                  | 57,200                  |

Dated: June 1, 2009.

**Maryam I. Daneshvar,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0251]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; User Fee Cover Sheet; Form FDA 3397

**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 (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 Form FDA 3397, User Fee Cover Sheet, that must be submitted along with certain drug and biologic product applications and supplements.

**DATES:** Submit written or electronic comments on the collection of information by August 7, 2009.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

**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 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 extension 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 set forth in this document.

With respect to the following collection of information, FDA invites comment on these topics: (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.

#### User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910-0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102-571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 107-188), and most recently by the Food and Drug Administration