Dated: February 24, 2010.

**Maryam I. Daneshvar,**

*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–10–10BT]**

### 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.*

*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 Quitline Data Warehouse — 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 since its peak in the 1960s, overall smoking prevalence among U.S. adults has remained virtually unchanged during the past five years. Large disparities in smoking prevalence continue to exist among members of racial/ethnic minority groups and individuals of low socioeconomic status.

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. The NTCP has provided funding for State quitlines, which provide telephone-based tobacco cessation services—including individualized counseling and self-help material—to help tobacco users quit. Quitlines overcome many of the barriers to tobacco cessation classes and traditional clinics because they are free and available at the caller's convenience. Quitline services in all States can be accessed through a toll-free national portal number at 1–800–QUIT–NOW. According to CDC's Best Practices for Comprehensive Tobacco Control, approximately six to eight percent of tobacco users potentially can be reached successfully by quitlines; however, currently, only one to two percent of tobacco users contact quitlines.

All States collect intake information about quitline callers and the services provided to them, but have varied with respect to the schedule for follow-up with callers, the number of follow-up attempts per caller, and the collection of information related to follow-up. With leadership from the North American Quitline Consortium (NAQC) and other tobacco control organizations, the field has collaborated to develop a Minimum Data Set (MDS) consisting of a set of suggested intake questions that should be asked of all callers, and follow-up questions that should be asked of a representative sample of callers who have both completed intake and received a quitline service.

CDC requests OMB approval to collect information for a National Quitline Data Warehouse (NDQW) based on a uniform follow-up protocol and standardized instruments adapted from the MDS. Respondents will be the 50 States, the District of Columbia, and Guam. Additional funding for the expansion of tobacco quitline services, standardization of the information collection, and transmission to the shared NQDW is provided under the *American Recovery and Reinvestment Act of 2009* (ARRA).

Intake information will be collected from approximately 60,833 callers per month over a 24-month period. Minimal information will be collected from callers who contact the Quitline on behalf of another person. The information collection will also include seven-month follow-up data from a random sample of approximately 3,400 callers per month across all States, beginning in month eight (*i.e.,* seven full months after the first intakes) and continuing through month 24. Finally, the Tobacco Control Manager for each ARRA awardee (State, district or territory) will be required to submit a quarterly report describing services provided. The quarterly report will be used to quantify improvements in the capacity of the quitlines to assist tobacco users over time and to evaluate the expenditure of Recovery Act dollars.

The NQDW will have significant implications for the development of policies and programs aimed at tobacco use cessation and reduction of tobacco use. The information to be collected in the NQDW will be used to determine the role quitlines are playing in promoting tobacco use cessation, measure the number of tobacco users being served by State Quitlines, determine reach of quitlines to high-risk populations (*e.g.,* racial and ethnic minorities and the medically underserved), measure the number using each State quitline who quit, determine whether some combinations of services contribute to higher quit rates than others, and improve the timeliness, access to, and quality of data collected by quitlines.

CDC requests OMB approval to collect information for a two-year period. All information will be collected electronically. There are no costs to respondents other than 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) |
|---|---|---|---|---|---|
| Caller who contacts the Quitline on behalf of someone else. | Intake Questionnaire | 230,000 | 1 | 1/60 | 3,833 |
| Caller who contacts the Quitline for personal use. | | 500,000 | 1 | 10/60 | 83,333 |
| Quitline caller who received a Quitline service. | Follow-up Questionnaire | 28,900 | 1 | 7/60 | 3,372 |
| Tobacco Control Manager | Quitline Services Questionnaire | 52 | 4 | 7/60 | 24 |
| Total | | | | | 90,562 |

Dated: February 23, 2010.

**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–2010–N–0084]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Pretesting of Tobacco Communications

**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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on pretesting of tobacco communications.

**DATES:** Submit written or electronic comments on the collection of information by April 30, 2010.

**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, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, e-mail: *Jonnalynn.capezzuto@fda.hhs.gov*.

**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 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 comments 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.

**Pretesting of Tobacco Communications**

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 903(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) and to develop stronger health warnings on tobacco packaging as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), it is beneficial for FDA to conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)). In conducting such research, FDA will employ formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences. The information collected will serve two major purposes. First, as formative research it will provide the critical knowledge needed about target audiences. FDA must first understand critical influences on people's decisionmaking process when choosing to use, not use, or quit using tobacco products. In addition to understanding the decisionmaking processes of adults, it is also critical to understand the decisionmaking processes among adolescents (ages 13 to 17), where communications will aim to discourage tobacco use before it starts. Knowledge of these decisionmaking processes will be applied by FDA to help design effective communication strategies, messages, and warning labels. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. By utilizing appropriate qualitative and quantitative methodologies, FDA will be able to: (1) Better understand characteristics of the target audience-its attitudes, beliefs, and behaviors-and use