

baseline and post-campaign survey will be conducted with adolescents, their parents and their teachers to determine outcomes of the campaign including attitudes, beliefs and intended behaviors toward IPV and sexual violence both before and after implementation of the campaign. The baseline information collected prior to the campaign launch will assist CDC in tailoring the communication materials to each of the middle schools and community groups selected from the target markets. The

evaluation will then utilize these baseline measures along with the information collected following implementation to assess the campaign's success at decreasing IPV-tolerant attitudes, increasing the identification of appropriate ways to respond in situations that could lead to IPV, and increasing the awareness of resources to help facilitate discussions about appropriate dating behavior.

The pre-post research design of this campaign evaluation will aid CDC in

assessing the changes in attitudes, beliefs and behaviors associated with the campaign.

The goal of CDC's Media Campaign, Choose Respect, is to increase the perception among adolescents that any form of violence between intimate partners, whether physical, verbal or sexual is considered inappropriate and unacceptable. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden hours
Teachers Baseline Survey .....	600	1	15/60	150
Parents Baseline Survey .....	6000	1	15/60	1500
Adolescents Baseline Survey .....	6000	1	25/60	2500
Teachers Post-campaign Survey .....	600	1	15/60	150
Parents Post-campaign Survey .....	6000	1	15/60	1500
Adolescents Post-campaign Survey .....	6000	1	25/60	2500
Total .....	25,200	.....	.....	8300

Dated: December 7, 2005.

Joan F. Karr,

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-06-06AL]

**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 404-639-4766 or 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.

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**

Customer Surveys Generic Clearance for the National Center for Health Statistics -New-National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

As part of a comprehensive program, the National Center for Health Statistics (NCHS) plans to assess its customers' satisfaction with the quality and relevance of the information it produces. NCHS will conduct voluntary customer surveys to assess strengths in agency products and services. Results of these surveys will be used in future planning initiatives. This is a request for

a generic approval from OMB to conduct customer surveys over the next three years.

The data will be collected using a combination of methodologies appropriate to each survey. These may include: Evaluation forms, Mail surveys, Focus groups, Automated and electronic technology (e.g., e-mail, Web-based surveys), and Telephone surveys.

Systematic surveys of several groups will be folded into the program. Among these are Federal customers and policy makers, state and local officials who rely on NCHS data, the broader educational, research, and public health community, and other data users. The 2006 surveys will include: (1) a self-selected broad-based group of data users who register for and/or attend NCHS sponsored conferences and (2) all persons who access the NCHS Website. Data items will include (in broad categories) information regarding an individual's gender, age, occupation, affiliation, location, etc. The proposed questions will attempt to obtain information that will characterize the respondents' familiarity with and use of NCHS data, their assessment of usefulness, general satisfaction with available services and products, and suggestions for improvement of services and products. There is no cost to respondents other than their time to participate in the survey.

## ESTIMATED ANNUALIZED BURDEN TABLE

Type of survey	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden hours
Questionnaire for conference registrants/attendees .....	1,000	1	15/60	250
Focus groups .....	80	1	1	80
Web-based .....	1,000	1	20/60	333
Other customer surveys .....	400	1	15/60	100
Total .....				763

Dated: December 8, 2005.

**Joan F. Karr,**

*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. 2005N-0016]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs: Study 1

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by January 17, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA

has submitted the following proposed collection of information to OMB for review and clearance.

#### Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Study 1

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the act. Under the act, a drug is misbranded if it's labeling or advertising is false or misleading. In addition, section 502(n) of the act (21 U.S.C. 352(n)) specifies that advertisements for prescription drugs and biological products must provide a true statement of information “\* \* \* in brief summary \* \* \*” about the advertised product’s “\* \* \* side effects, contraindications and effectiveness \* \* \*.” Generally, the display text of an advertisement presents a fair and balanced disclosure of the product’s indication and benefits and the product’s side effects and contraindications. The prescription drug advertising regulations (§ 202.1(e)(3)(iii) (21 CFR 202.1(e)(3)(iii))) specify that the information about risks must include each specific side effect and contraindication from the advertised drug’s approved labeling. The regulation also specifies that the phrase “side effect and contraindication” refers to all of the categories of risk information required in the approved product labeling written for health professionals, including the Warnings, Precautions, and Adverse Reactions sections. Thus, every risk in an advertised drug’s approved labeling must be addressed to meet these regulations.

In recent years, FDA has become concerned about the adequacy of the brief summary in DTC print advertisements. Although advertising of

prescription drugs was once primarily addressed to health professionals, consumers increasingly have become a primary target audience, and DTC advertising has dramatically increased in the past few years. Results of the FDA 2002 survey on DTC advertising (available at <http://www.fda.gov/cder/ddmac/researchka.htm>) provide some information regarding the extent to which consumers read these ads and the brief summary that accompanies the main ad—41 percent of respondents in 2002 reported they do not usually read any of the brief summary. Use of the brief summary is a function of whether they have an interest in the condition; about 45 percent of those having a particular interest in the advertised drug read all or almost all of the brief summary.

Because the regulations do not specify how to address each risk, sponsors can use discretion in fulfilling the brief summary requirement under § 202.1(e)(3)(iii). Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert, professional labeling, or prescribing information). This labeling is written for health professionals, using medical terminology. FDA believes that while this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, this method may be difficult for consumers to understand.

Consumers may use the brief summary for many purposes, such as to learn about new treatments, to compare with OTC medications, to form a benefit-risk judgment, to make brand comparison, to generate questions for their healthcare provider, and to verify promotional claims. All of these possible uses contribute to achieving more informed healthcare decisions.

These different uses likely involve different mental processing strategies, therefore a balanced assessment of possible changes in the format and content of the brief summary is necessary. FDA’s objectives for communicating important information