

For Further Information Contact:
Sandra M. Peay, Contact Representative,
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Representative, Federal Trade
Commission, Premerger Notification
Office, Bureau Of Competition, Room
H-303, Washington, DC 20580, (202)
326-3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Disease Control and
Prevention**

[60-Day-08-08BP]

**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 Maryam 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

Audience Profiling for Carbon Monoxide Poisoning Prevention Status—New—National Center for Environmental Health (NCEH), Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Carbon monoxide (CO) is one of the leading causes of poison-related deaths in the United States. The Centers for Disease Control and Prevention (CDC) estimates that each year approximately 500 people die of unintentional, nonfire-related CO exposure, and another 15,000 individuals visit emergency rooms for treatment from exposure to CO gas.

Despite our current knowledge of scenarios and products that lead to CO poisoning, questions remain about when and how individuals use CO-emitting

products, why they engage in certain risk behaviors, how best to inform them about the CO poisoning, and how receptive they are to existing prevention materials. This study aims to address these questions through assessing the basis for current audience knowledge, attitudes, and practices and, ultimately, strengthen educational materials about CO poisoning prevention.

The study will employ the use of qualitative methods during three phases of data collection. Phase I will consist of eight in-person focus groups among home furnace owners and portable generator owners (n=64) as well as four telephone interviews with organizations that serve populations at risk for CO poisoning (n=4). Phase II will consist of analyzing previously collected data on consumer media usage and preferences. Phase III will consist of 16 in-person triad interviews (3 individuals per interview) with home furnace owners and portable generator owners (n=48) to pretest CO poisoning educational materials.

NCEH will identify individuals for the focus groups and triad interviews using recruiting firms that specialize in the two at-risk populations: 1. home furnace owners and 2. portable generator owners. Individuals in these two groups will be screened over the telephone by the recruiting firms, and if they meet the eligibility criteria, will be invited to participate in the study. At the end of each focus group and triad interview, NCEH will ask participants to complete a brief exit questionnaire on demographics and media usage.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondents (focus group, phone interview, and triad participants) | Instrument type | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|--------------------------------------------------------------------|----------------------------|-----------------------|------------------------------------|----------------------------------------|-------------------------|
| Owners of Gas or Oil Burning Household Appliances. | Focus Group Screener | 64 | 1 | 10/60 | 11 |
| | Focus Group | 32 | 1 | 2 | 64 |
| | Exit Questionnaire | 32 | 1 | 10/60 | 5 |
| | Triad Screener | 48 | 1 | 10/60 | 8 |
| | Triad | 24 | 1 | 2 | 48 |
| Owners of Portable Gas Burning Generator. | Focus Group Screener | 64 | 1 | 10/60 | 11 |
| | Focus Group | 32 | 1 | 2 | 64 |
| | Exit Questionnaire | 32 | 1 | 10/60 | 5 |
| | Triad Screener | 48 | 1 | 10/60 | 8 |
| | Triad | 24 | 1 | 2 | 48 |
| Expert | Telephone Interview | 4 | 1 | 1 | 4 |
| Total | | | | | 276 |

Dated: September 11, 2008.

Maryam 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-2008-N-0490]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program

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 the collection of information associated with the Voluntary Cosmetic Registration Program.

DATES: Submit written or electronic comments on the collection of information by November 17, 2008.

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 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.

Voluntary Cosmetic Registration Program—21 CFR Part 720 (OMB Control Number 0910-0030)—Extension

The Federal Food, Drug, and Cosmetic Act (the act) provides FDA with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, the agency has developed the Voluntary Cosmetic Registration Program (VCRP). In part 720 (21 CFR part 720), FDA requests that firms that manufacture, pack, or distribute cosmetics file with the agency an ingredient statement for each of their products. Ingredient statements for new submissions (§§ 720.1 through 720.4) are reported on Form FDA 2512, “Cosmetic Product Ingredient Statement,” and on Form FDA 2512a, a continuation form. Amendments to product formulations (§§ 720.3, 720.4, and 720.6) also are reported on Forms

FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, “Discontinuance of Commercial Distribution of Cosmetic Product Formulation” (§§ 720.3 and 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA's online filing system, intended to make it easier to participate in the VCRP, was made available industry-wide on December 1, 2005. The online filing system is available on FDA's VCRP Web site at <http://www.cfsan.fda.gov/~dms/cos-regn.html>. The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512. The agency strongly encourages electronic filing of Form FDA 2512 because it is faster and more convenient. A filing facility will receive confirmation of electronic filing by e-mail. Submission of the paper version of Forms FDA 2512, 2512a, and 2514 remains an option as described in <http://www.cfsan.fda.gov/~dms/cos-reg2.html>. However, due to the high volume of online participation, the VCRP is allocating its limited resources primarily to electronic filings.

FDA places cosmetic product filing information in a computer data base and uses the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, voluntary filings provide FDA with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. The information also is used in defining and planning analytical and toxicological studies pertaining to cosmetics.

Information from the database is releasable to the public under FDA compliance with the Freedom of Information Act. FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry.

FDA estimates the burden of this collection of information as follows: