exposure potential. That information represents an individual's exposure history. With these data, we can assess the presence or absence of a specific exposure and estimate how long and how frequently people have had contact with the chemical(s) of interest. The responses also provide data about exposure to other sources of the chemical(s).

Participation in an EI is completely voluntary and requires participants' written consent. To assist in interpreting the sampling results, a survey questionnaire appropriate to the specific contaminant is administered to participants. Information is generally gathered in a face-to-face interview with potentially exposed participants, but could occasionally be administered by phone or mail. All information is usually collected and recorded electronically and, on occasion, hard copy forms will be used.

ATSDR uses approximately 12–20 questions about environmental exposures per investigation. This number can vary depending on the number of chemicals being investigated the route of exposure (e.g., breathing, eating, touching), and number of other sources of the chemical(s) (e.g., products used, jobs).

Typically, the number of participants in an individual EI ranges from 10 to 100. Questionnaires are generally needed in less than half of the EIs (approximately than 12 per year).

The DCHI SSB EI team and the ATSDR staff and partners in the DCHI cooperative agreement program will use the EI Generic Clearance for OMB submittals for each EI. EIs are usually nonresearch investigations, but occasionally may be classified as research. The DCHI cooperative agreement operates across ten ATSDR regions across the nation. In 2012, ATSDR was functionally reorganized and DCHI was divided into three functional units that administer its ten regions and its cooperative agreement program: Eastern Branch, Central Branch and Western Branch. The DCHI SSB supports all three DCHI branches. It is uncertain at this time how many EIs across the states, regions, and branches will require an expedited approval at the same time.

EI participants will likely include community members that are concerned about being exposed to environmental contamination. Investigations tend to focus on the most highly exposed at the site, such as those living in proximity to the site. On occasion, small businesses may be included as EI participants.

The estimated annual burden hours are 600, which is an increase from the previously approved burden hours of 375 hours. The increase is due to the addition of EIs conducted by cooperative agreement states requiring a survey each year. There are no costs to the respondents other than their time.

EIs are performed under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the ''Superfund'' Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Exposure Investigation Participants	Chemical Exposure Questions	1,200	1	30/60

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–13PR]

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 404–639–7570 or send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email 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

Evaluating the Implementation and Outcome of Policy and Environmental Cancer Control Activities—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Through the National Comprehensive Cancer Control Program (NCCCP), CDC provides cooperative agreement funding to 65 health departments in states, the District of Columbia, tribal organizations, and territories. NCCCP funding is used to design, implement, and evaluate comprehensive cancer control plans (CDC–RFA–DP12–1205). Support for these programs is a cornerstone of CDC efforts to reduce the burden of cancer throughout the nation. NCCCP awardees have consistently included policy, system and environmental (PSE) change strategies in their program plans and initiatives.

In 2010, CDC provided additional funding (CDC–RFA–DP10–1017) to 13 NCCCP awardees to increase their focus on PSE change strategies. The 13 funded pilot programs include: Cherokee Nation, Colorado, Florida, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, New York, Oregon, Utah, and Wisconsin. The goal of the pilot is to examine what a modest

investment can yield, building on the successes that NCCCP awardees have already experienced. Pilot program funding aims to increase each awardee's capacity to implement PSE change initiatives, to effectively implement policies that address local priorities, and to increase collaboration with both traditional and nontraditional partners.

CDC plans to collect the information needed to describe the implementation and outcomes of the pilot program, and to compare the experiences of pilot program awardees with the experiences NCCCP awardees that did not receive pilot program funding. Information collection will include a web-based survey of all NCCCP program directors, a longitudinal case study of selected pilot program awardees, a survey of pilot program coalition members, and focus groups with individuals who have provided technical assistance (TA) to pilot program awardees.

The self-administered NCCCP program director survey will be completed at two points in time approximately 18–24 months apart. The survey will include questions that address capacity for PSE change, technical assistance and training, and descriptive information about two PSE change initiatives being undertaken. The estimated burden per response is 30 minutes.

The longitudinal, multiple-site case study will be conducted with six awardees that received pilot program funding. In selecting case study sites, CDC will consider features that are expected to influence PSE change processes and outcomes, such as: the structure of the awardee's public health system, the state/local policy climate, the awardee's capacity for PSE change, the focus areas that awardees have chosen to address in their work plans, and the demographics and population characteristics of the awardee's jurisdiction. One individual at each site will be asked to assist in coordinating a site visit.

During initial site visits to the six selected pilot programs, interviews will be conducted with key informants including NCCCP staff, partners who are members of the awardee's policy task force, and community members who play an important role in implementing PSE change initiatives. Approximately three NCCCP staff members and 12 partners/community members per site will be asked to participate. The estimated burden per response is 90 minutes for NCCCP staff and 60 minutes for partners/community members. Interview data will be supplemented with documentary evidence and program monitoring data already collected by local program staff and by CDC. Approximately two years after the site visit, a second round of interviews will be conducted by telephone. The respondents for the telephone interviews may be the same individuals who were interviewed during the initial site visits, or other key informants.

CDC also plans to conduct an annual focus group involving CDC staff and national partners who have provided technical assistance and training to the pilot programs. The purpose of the focus groups is to gather information about the capacity, challenges, and facilitators of PSE change from the perspective of the trainers who have had direct interaction with the awardees. Focus groups will be conducted with approximately 10 non-federal respondents per group. The estimated burden per response is 90 minutes.

Finally, CDC plans to conduct a survey of coalition members in the third year of the evaluation. The content of the survey may include questions from the program director survey as well as other issues identified during the evaluation process. CDC estimates 20 responses in each of 13 sites for a total of 260 responses. The estimated burden per response is 20 minutes.

Specific evaluation questions to be addressed in this pilot program evaluation include: (1) How the pilot program enhanced comprehensive cancer control; (2) whether the pilot program facilitated a shift towards primary prevention; (3) the program's effects on cancer control infrastructure; (4) pilot program implementation strategies; (5) key outcomes; (6) the role of the state task force; and (7) lessons learned.

The case studies will allow CDC to understand how differences in programmatic characteristics and context influence overall implementation processes and outcomes. Information to be collected may also inform the development of technical assistance and the future allocation of program resources.

OMB approval is requested for three years. Participation is voluntary and there are no costs to the 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 hr)	Total response burden (in hr)
CCC Program Directors	Program Directors Web Survey Questionnaire.	43	1	30/60	22
CCC Staff	Key Informant Selection	2	1	8	16
	Key Informant Recruitment/Scheduling.	12	1	5/60	1
	Key Informant Interview	12	1	1.5	18
CCC Partners	Key Informant Recruitment/Scheduling.	48	1	5/60	4
	Key Informant Interview	48	1	1	48
	Coalition Survey	87	1	20/60	29
TA Providers	Focus Group Guide	10	1	1.5	15
Total					153

Dated: April 1, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0977]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

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 May 8, 2013.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0312. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

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.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents—21 CFR Part 1140 (OMB Control Number 0910–0312)—Revision

This is a request for an extension of OMB approval of the information collection requirements contained in FDA's regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21 CFR part 1140 (previously codified at 21 CFR part 897) are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions—which included striking subpart C (with § 897.24) and § 897.32(c) from the reissued rule (section 102(a)(2)(B). The reissued final rule was published in the **Federal Register** on March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30, which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations. Disclosure requirements for § 1140.32 state that the advertising must use black text on a white background, but that this particular requirement does not apply to adult newspapers, magazines, periodicals, or other publications. Recordkeeping requirements under § 1140.32 indicate that competent and reliable survey evidence is required to determine whether a particular publication is an ''adult'' publication.

The requirements are as follows:

- Reporting—§ 1140.30 directs persons to notify FDA if they intend to use a form of advertising that is not described in § 1140.30(a)(1).
- Disclosure—§ 1140.32 requires firms to use black text on white backgrounds in labeling and advertising.
- Recordkeeping—§ 1140.32 indicates that firms advertising in ''adult'' magazines or publications may need survey evidence demonstrating that the publication meets the criteria for an ''adult'' publication.

For the disclosure and recordkeeping requirements under § 1140.32, FDA has decided to use its discretionary enforcement and has placed placeholders of 1 burden hour for disclosure and 1 burden hour for reporting because FDA does not intend to enforce the requirements for this section for the next 3 years.

In the **Federal Register** of September 28, 2012 (77 FR 59622), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30 (Scope of permissible forms of labeling and advertising)	300	1	300	1	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1140.32 (Format and content requirements for labeling and advertising)	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.