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 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

Evaluation of the Effectiveness of the Smoke Alarm Installation and Fire Safety Education (SAIFE) Program—Extension—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project seeks a one year extension of its OMB PRA clearance for data collection. Due to early project delays in obtaining clearances for data collection, the project was unable to start as planned and missed evaluating one program cycle, with a program cycle running for approximately one year. This extension is necessary in order to complete the projects original design of evaluating three program cycles of the SAIFE program as implemented in the State of North Carolina. An extension will allow completion of the evaluation of the third and final cycle of the program.

This project will use data from in-person interviews, paper and telephone surveys to assess the effectiveness of the Smoke Alarm Installation and Fire Safety Education (SAIFE) program and its efficacy in delivering fire safety information. The data will be collected from a convenience sample of adults 18 years of age or older who volunteer to participate in the SAIFE program. A total of 360 households will complete the evaluation each year of the data collection for a mass total of 1080 households over the next three years. Participants will be asked to complete a 15-minute survey at two points, once immediately before the intervention and then 6 months afterwards. The survey will assess outcome measures including, but not limited to, changes in knowledge, attitudes, beliefs, and behaviors regarding various aspects of fire safety and prevention; changes in reported residential fire-related injuries and deaths; increased or decreased presence of functioning smoke alarms; and the costs associated with the SAIFE intervention. The evaluation will measure these changes across time, between groups and within groups, among communities that will receive the SAIFE intervention.

CDC programs are currently funded in 16 states to provide for home installation of smoke alarms plus general fire safety education in households at high risk for fire and fire related injury and death. Programs of this type are intended to prevent fire related injury and mortality, but have not been studied scientifically to assess their impact on fire-related injury outcomes. The proposed study represents the first formal effort to evaluate the effectiveness and cost implications of the SAIFE program as implemented in North Carolina. The data collected in this study will have the potential to inform other smoke alarm installation programs, as well as indicate future priorities in prevention and preparedness for residential household fires. The only cost to the participant is the time involved to complete the surveys.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden (in hours)
Adult male and female (age 18+ years) screened	425	1	5/60	35
Adult male and female (age 18+ years) Pre/Post Evaluation survey	360	2	15/60	180
Adult male and female (age 18+ years) household visit	36	1	1	36
Total				251

Dated: June 3, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–13411 Filed 6–8–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–0780]

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 the CDC Reports Clearance Officer at 404–639–5960 or send comments to CDC/ATSDR 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

National Survey of Residential Care Facilities (NSRCF), (OMB No. 0920–0780)—Revision— National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, ''shall collect statistics on health resources * * * [and] utilization of health care, including extended care facilities, and other institutions.''

In 2008, NCHS sought approval for a pretest and full survey of The National Survey of Residential Care Facilities (NSRCF). OMB approved only the pretest which has been completed. NCHS now seeks approval to collect the full survey. The survey is designed to complement data collected by other federal surveys and to fill a significant data gap about a major portion of the long-term care population. Data from NSRCF will provide information on residential care facilities that policymakers, providers, and researchers can use to address a wide array of policy and research questions. The survey will utilize a computer-assisted personal interviewing (CAPI) system to collect information about facility and resident characteristics. This computerized system speeds the flow of data and makes it possible to release information on a timelier basis and easier for respondents to participate in the survey. The CAPI system may also enhance data quality. Clearance for two years is requested.

A stratified random sample of residential care facilities across four strata (small, medium, large and very large) will be selected to participate in NSRCF. Within each facility a random sample of residents will be selected. To be eligible a facility must be licensed, registered, listed, certified, or otherwise regulated by the State; provide room and board with at least two meals a day; provide around-the-clock on-site supervision; help with activities of daily living (*e.g.,* bathing, eating, or dressing) or medication supervision; serve primarily an adult population; and have at least four beds.

The facility questionnaire will collect data about facility characteristics (*e.g.,* size, age, types of rooms), services offered, characteristics of the resident population, facility policies and services, charges for services, and background of the director. The resident questionnaire collects information on resident demographics, current living arrangements within the facility, involvement in activities, use of services, charges for care, health status, and cognitive and physical functioning. For the national survey, approximately 2,250 facilities will be surveyed for an annual average of 1,125 facilities. Information on an average of 4 residents will be collected from an annual average of 1,125 facility staff. Residents themselves will not be interviewed.

Users of NSRCF data include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation and the Agency for Healthcare Research and Quality; and associations, such as the American Association of Homes and Services for the Aging, National Center for Assisted Living, American Seniors Housing Association, Assisted Living Federation of America; universities; foundations; and other private sector organizations. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Name of form	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Response burden in hours
Facility Director	Facility Screener	1125	1	10/60	188
Facility Director	Resident Selection	1125	1	10/60	188
Facility Director	Pre-Interview Worksheet	1125	1	15/60	281
Facility Director	Facility Questionnaire	1125	1	1.25	1,406
Facility Director or Staff Member	Resident Questionnaire	1125	4	20/60	1,500
Total					3,563

Dated: June 3, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–13409 Filed 6–8–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0148] (formerly Docket No. 2007D–0493)

International Conference on Harmonisation; Guidance on Q8(R1) Pharmaceutical Development; Addition of Annex; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q8(R1) Pharmaceutical Development.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH Q8(R1) guidance includes the previously published parent guidance entitled ''Q8 Pharmaceutical Development'' (Q8 parent guidance) (71 FR 29344; May 22, 2006) and a newly added annex. The annex provides