Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Laboratory Medicine Best Practices Project (LMBP)—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (proposed), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking approval from the Office of Management and Budget (OMB) to collect information from healthcare organizations in order to conduct a systemic review of laboratory practice effectiveness. The purpose of information collection is to include completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics) in systematic reviews of practice effectiveness. CDC has been sponsoring the Laboratory Medicine Best Practices (LMBP) initiative to develop new systematic evidence reviews methods for making evidence-based recommendations in laboratory medicine. This initiative supports the CDC's mission of improving laboratory practices.

The focus of the Initiative is on pre- and post-analytic laboratory medicine practices that are effective at improving health care quality. While evidence-based approaches for decisionmaking have become standard in healthcare, this has been limited in laboratory medicine. No single-evidence-based model for recommending practices in laboratory medicine exists, although the number of laboratories operating in the United States and the volume of laboratory tests available certainly warrant such a model.

The Laboratory Medicine Best Practices Initiative began in October 2006, when Division of Laboratory Systems (DLS) convened the Laboratory Medicine Best Practices Workgroup (Workgroup), a multidisciplinary panel of experts in several fields including laboratory medicine, clinical medicine, health services research, and health care performance measurement. The Workgroup has been supported by staff at CDC and the Battelle Memorial Institute under contract to CDC.

To date, the Laboratory Medicine Best Practices (LMBP) project work has been completed over three phases. During Phase 1 (October 2006–September 2007) of the project, CDC staff developed systematic review methods for conducting paper reviews related to the effectiveness of laboratory medicine practices. Results of a review of practices that reduce patient specimen identification indicated that an insufficient quality and number of published studies were available for completing systematic evidence reviews of laboratory medicine practice effectiveness for multiple practices. These results were considered likely to be generalizable to most potential review topics of interest. A finding from Phase 1 work was that laboratories would be unlikely to publish quality improvement projects or studies demonstrating practice effectiveness in the peer reviewed literature, but that they routinely conducted quality improvement projects and had relevant data for completion of evidence reviews. Phase 2 (September 2007–November 2008) and Phase 3 (December 2008–September 2009), involved further development of methods to obtain and critically appraise published and unpublished data. A pilot test of a standardized data collection form with less than nine potential laboratory respondents supported the Phase 1 finding that data from completed laboratory medicine quality improvement projects could supplement published evidence in systematic reviews. The objective for successive LMBP evidence reviews of practice effectiveness is to supplement the published evidence with unpublished evidence to fill in gaps in the literature.

Healthcare organizations and facilities (laboratories, hospitals, clinics) will have the opportunity to voluntarily enroll in an LMBP network and submit readily available unpublished studies; quality improvement projects, evaluations, assessments, and other analyses relying on unlinked, anonymous data using the LMBP Submission Form. LMBP Network participants will also be able to submit unpublished studies/data for evidence reviews on an annual basis using this form. There will be no charge to respondents for their participation, other than their time. The total estimated annualized burden hours for this information collection request are 138 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Healthcare Organizations	150	1	55/60

Date: March 11, 2010.

Maryam I. Daneschvar,

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

[FR Doc. 2010–5843 Filed 3–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–10–10CB]

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 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

A Survey to Evaluate Occupational Safety and Health Educational Materials for Home Care Workers—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. Under Public Law 91–596, Sections 20 and 22 (section 20–22, Occupational Safety and Health Act of 1970), NIOSH has the responsibility to conduct research to advance the health and safety of workers. In this capacity, NIOSH will conduct a survey of home care workers to evaluate newly developed educational intervention materials.

Home care workers who provide housekeeping and routine personal care services to elderly, disabled or ill individuals in their homes, constitute one of the fastest growing occupational groups, estimated at about 1,500,000 workers. In 1997, the U.S. Bureau of Labor Statistics issued a special report on work-related injuries to home care workers showing an injury rate which was 50% higher than that of workers employed in the private hospital sector and 70% higher than the overall rate for all private industry workers.

NIOSH has developed educational intervention materials for home care workers to prevent exposure to work-related hazards. The intervention materials consist of a printed handbook and a training session that explains how to use the handbook. The primary goal of the handbook and training session is to help home care workers and their clients identify hazards, discuss these hazards and identify accessible and low cost tips and tools for minimizing exposures to hazards. These materials have been developed and piloted in Alameda County, California. The goal of this data collection is to evaluate these materials before disseminating them more broadly.

The study population for this survey includes current home care workers and their clients who are enrolled in the In-Home Supportive Services (IHSS) Program in Alameda County, California.

NIOSH has obtained input on the content and operational aspects of the survey through local stakeholder meetings. The survey instrument has been reviewed by subject matter experts and cognitive interviews have been conducted using the survey instrument. Input received was used to guide development of the survey instrument and plans for survey implementation.

All Alameda County IHSS home care workers will be invited to participate. Volunteers will complete a brief interest response form which will be returned to the study contractor and the first 320 eligible volunteers will be randomized into either an intervention or a control group. The primary client for each home care worker participant will also be invited to participate but the clients' willingness to participate will not affect whether a home care workers can remain as a study participant. Both the home care worker and their primary client will complete two telephone surveys with a two month interval between the two surveys. Data from the telephone survey will be captured directly into an electronic database. For the intervention group the home care workers will receive the intervention materials and training during the interval between the two surveys. The control group will receive their intervention materials and training after the completion of the second survey. Each telephone survey will last approximately 30 minutes for home care workers and 15 minutes for clients. Because of the demographics of the population intervention materials as well as the evaluation surveys are in three languages: English, Spanish and Chinese.

Information will be collected on demographic variables including age, sex, race, education, income, primary language, and marital status. Information will be collected on the number of years a worker has been employed as a home care worker and the number of years a client has received home care services. Information will also be collected on working conditions and occupational exposures, work related injuries, knowledge of work-related health risks and workers' perception of the ease of controlling hazards. Finally, information will be collected from workers on their job satisfaction and clients on their satisfaction with caregiver services, on the quality of the caregiver and client relationships, and specific questions regarding use of the intervention materials.

The purpose of this information collection is to evaluate whether or not the educational materials (the Home Care Worker Handbook and training session) are effective in (1) conveying the intended message and (2) encouraging home care workers and their clients to make changes to reduce hazards. Without benefit of the evaluation, CDC will be unable to determine the effectiveness of the materials or formulate recommendations on their appropriate use and broader dissemination.

Once the study is completed, results will be made available via various means including the NIOSH internet site. NIOSH expects to complete data collection no later than winter of 2011. There is no cost 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)
Home care workers	Worker interest response form	1500	1	2/60	50
	Worker survey (pre)	320	1	30/60	160
	Worker Training program	320	1	1	320
	Worker survey (post)	320	1	30/60	160
Home care clients	Client survey (pre)	320	1	15/60	80
	Client survey (post)	320	1	15/60	80

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total					850

Dated: March 11, 2010.

Maryam I. Daneshvar,

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

[FR Doc. 2010–5841 Filed 3–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities: Proposed Collection; Comment Request; Prescription Drug Advertisements

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 the reporting requirements, including third party disclosure, contained in FDA's regulations on prescription drug advertisements.

DATES: Submit written or electronic comments on the collection of information by May 17, 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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, e-mail: *Elizabeth.Berbakos@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.

Prescription Drug Advertisements—21 CFR 202.1 (OMB Control Number 0910)—New

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, section 502(n) of the act requires advertisements to contain "a true statement" of certain information including "information in brief summary relating to side effects, contraindications, and effectiveness" as required by regulations issued by FDA. FDA's prescription drug advertising regulations at § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement." If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of the act (21 U.S.C. 352(n) and 321(n)), and FDA's implementing regulations at § 202.1(e).

Advertisements subject to the requirements at § 202.1 are subject to the PRA because these advertisements disclose information to the public. In addition, § 202.1(e)(6) and (j) include provisions that are subject to OMB approval under the PRA. The information collection requirements in § 202.1 have not previously been submitted to OMB for approval. With this notice, we are seeking comment on the proposed information collection.

Reporting to FDA

Section 202.1(e)(6) includes a provision that is subject to the PRA. Section 202.1(e)(6) permits a person who would be adversely affected by the enforcement of a provision of § 202.1(e)(6) to request a waiver from FDA for that provision. The waiver request must set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of § 202.1(e)(6) from which a waiver is sought, a complete copy of the