The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. FDA therefore concludes that any additional burden and costs in recordkeeping based on the new testing requirements for source and finished bottled water are negligible. FDA estimates that the labor burden of keeping records of each test is about 5 minutes per test. FDA also requires followup testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. FDA expects that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about 3 times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about 3 times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform positive sample, bottlers will then have to conduct a followup test for *E. coli*.

FDA expects that recordkeeping for the followup test for *E. coli* will also take about 5 minutes per test. As shown in table 1 of this document, FDA expects that 2.5 bottlers per year will have to carry out the additional *E. coli* testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, *E. coli* testing, and source rectification, FDA estimates a total burden of 179 hours. FDA bases its estimate on its experience with the current CGMP regulations.

Dated: October 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25927 Filed 10–27–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: A Generic Submission For Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources. *Type of Information Collection Request:* REVISION. *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection, diagnosis, and treatment to a wide variety of audiences and organizations (*e.g.,* cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations), it is beneficial for NCI, through its Office of Communications and Education (OCE), to pretest NCI communications strategies, concepts, and messages while they are under development. This pretesting, or formative evaluation, helps ensure that the messages, communication materials, and information services created by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since NCI's OCE also is responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, and management of NCI initiatives that address specific challenges in cancer research and treatment, it is also necessary to ensure that customers are satisfied with programs. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many educational programs and products that OCE and NCI produce. OCE will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and Web surveys) methodologies to conduct this formative and customer satisfaction research, allowing NCI to: (1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective communication tools and strategies; (2) use a feedback loop to help refine, revise, and enhance messages, materials, products, and programs—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and (3) expend limited program resource dollars wisely and effectively. This package represents the combination of a currently approved generic submission, ''Pretesting of NCI's Office of Communications Messages,'' (OMB No. 0925–0046) and a formerly approved generic submission, ''Customer Satisfaction with Educational Programs and Products of the NCI'' (OMB No. 0925–0526).

Frequency of Response: On occasion. *Affected Public:* Individuals or households; Businesses or other for profit; Not-for-profit institutions; Federal Government; State, Local, or Tribal Government. *Type of Respondents:* Adult cancer patients; members of the public; health care professionals; researchers; organizational representatives. The table below outlines the estimated burden hours required for a three-year approval of this generic submission. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES FOR BURDEN HOURS FOR THREE YEARS

[Generic study]

Survey method	Total number of respondents	Frequency of response	Minutes/hour per response	Total burden hours
Focus Groups	900	1	90/60 (1.5)	1,350.00
Individual In-Depth Interviews (Typically longer than 15 minutes, includes Web site usability testing)	600	1	45/60 (.75)	450.00
Brief Interviews (Typically less than 5 minutes)	19,000	1	10/60 (.17)	3,166.67
Surveys (Web, phone, in-person, paper-and-pencil)	12,500	1	10/60 (.17)	2,083.33
Totals	33,000			7,050.00

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nina Goodman, Senior Public Health Advisor, Office of Communications and Education (OCE), NCI, NIH, 6116 Executive Blvd., Suite 400, Rockville, MD 20892, call non-toll-free number 301–435–7789 or e-mail your request, including your address to: *goodmann@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: October 21, 2009.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E9–25954 Filed 10–27–09; 8:45 am]

BILLING CODE 4101–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10191]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Parts C and D Universal Audit Guide; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR Parts 422 and 423 Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. 42 CFR 422.502 describes CMS' regulatory authority to evaluate, through inspection or other means, Medicare Advantage Part C organizations. These records include books, contracts, medical records, patient care documentation and other records that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable. 42 CFR 423.503 states that CMS must oversee a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor. Section 423.514 states that the Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics regarding areas such as cost of operations, patterns of utilization availability, accessibility, and acceptability of services.

The rapid growth of these sponsoring organizations has forced CMS to update its current auditing strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy will reflect a move to more targeted, data-driven and risk-based audits. CMS will also focus on high-risk areas that have the greatest potential for beneficiary harm. The goal of the audits will be the earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors and Medicare Advantage organizations.

To accomplish these goals, we have combined all Part C and Part D audit elements into one universal guide which will also promote consistency, effectiveness and reduce financial and time burdens for both CMS and Medicare-contracting entities. Please refer to the crosswalk document for a list of changes. *Form Number:* CMS–10191 (OMB#: 0938–1000); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 195; *Total Annual Responses:* 195; *Total Annual Hours:* 24,180. (For policy questions regarding this collection contact Laura Dash at 410–786–8623. For all other issues call 410–786–1326).

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *November 27, 2009.*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: October 21, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–25993 Filed 10–27–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–10–09AX]

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