concept, message, and materials testing, one of which is focus groups. The purpose of focus groups is to ensure that the public and other key audiences, like health professionals, clearly understand cancer-specific information and concepts, are motivated to take the desired action, and do not react negatively to the messages.

Information collection will involve focus groups to assess numerous qualitative dimensions of cancer prevention and control messages, including, but not limited to, knowledge, attitudes, beliefs, behavioral intentions, information needs and sources, and compliance to recommended screening intervals. Insights gained from the focus groups will assist in the development and/or refinement of future campaign messages and materials. Respondents will include health care providers as well as members of the general public. Communication campaigns will vary according to the type of cancer, the qualitative dimensions of the message described above, and the type of respondents. DCPC has developed a set of example questions that can be tailored to screen for targeted groups of respondents, and a set of example questions that can be used to develop discussion guides for a variety of focus groups.

The average burden for each focus group discussion will be two hours. DCPC will conduct or sponsor up to 72 focus groups per year over a three-year period. An average of 12 respondents will participate in each focus group discussion. A separate information collection request will be submitted to OMB for approval of each focus group activity.

There are no costs to respondents except their time. The total estimated annualized burden hours are 1,814.

Estimated Annualized Burden Hours:

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health care providers and general public.	Screening Form	1,728	1	3/60	86
	Focus Group Discussion Guide	864	1	2	1728
Total					1814

Dated: August 10, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–20920 Filed 8–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–11–0802]

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 Daniel Holcomb, CDC 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

Active Bacterial Core Surveillance (ABCs) Projects—OMB 0920–0802, Expiration January 31, 2012 (Revision)—National Center for Immunization and Respiratory Disease (NCIRD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision to the approved data collection instruments for Active Bacterial Core surveillance (ABCs), to add supplemental questions for invasive methicillin-resistant *Staphylococcus aureus* (MRSA). CDC requests OMB approval to collect supplemental information to assess risk factors for invasive MRSA among patients recently discharged from acute care hospitals. Seventeen acute care facilities in 7 ABCs/EIP sites (CA, CT, CO, GA, NY, MN, TN) will participate in the collection of supplemental information for ABCs MRSA.

Preventing healthcare-associated invasive MRSA infections is one of CDC's priorities. Essential steps in reducing the occurrence of healthcare-associated invasive MRSA infections are to quantify the burden and to identify modifiable risk factors associated with invasive MRSA disease. The current ABCs MRSA surveillance has been essential to quantify the burden of invasive MRSA in the United States. Through this surveillance CDC was able to estimate that 94,360 invasive MRSA infections associated with 18,650 deaths occurred in the United States in 2005. The majority of these infections (58%) had onset in the community or within 3 days of hospital admission and occurred among individuals with recent healthcare exposures (healthcare-associated community-onset [HACO]). More recent data from the CDC's EIP/ABCs system have shown that two thirds of invasive HACO MRSA infections occur among persons who are discharged from an acute care hospital in the prior 3 months. Risk factors for invasive MRSA infections post-discharge have not been well evaluated, and effective prevention measures in this population remain uncertain.

The goal of the supplemental questions to be added to ABCs MRSA surveillance is to assess risk factors for invasive healthcare-associated MRSA infections, which will inform the development of targeted prevention measures. This activity supports the HHS Action Plan for elimination of healthcare-associated infections. This change will result in minimal impact on the current public burden.

An estimated total of 450 new patients (150 patients with HACO MRSA infection and 300 patients without HACO MRSA infection) will be contacted for the MRSA interview annually. This estimate is based on the numbers of MRSA cases reported by the EIP sites annually (*http://www.cdc.gov/abcs/reports-findings/survreports/mrsa08.html*) who are 18 years of age or older, had onset of the MRSA infection in the community or within 3 days of hospital admission, and history of hospitalization in the prior 3 months. There are no costs to respondents other than their time. The total response burden for the study is estimated as follows:

The OMB-approved ABCs MRSA form (#0920–0802) will be used to identify patients to be contacted for a telephone interview. These 450 patients will be screened for eligibility and those considered to be eligible will complete the telephone interview. We anticipate that 350 of the 450 patients screened will complete the telephone interview across all 7 EIP sites per year. We anticipate the screening questions to take about 5 minutes and the telephone interview 20 minutes per respondent.

TABLE—ESTIMATED BURDEN

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)	Total burden (in hours)
Hospital Patients	Screening Form	450	1	5/60	38
	Telephone interview	350	1	20/60	117
Total					155

Dated: August 10, 2011.

Daniel Holcomb,

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–2010–P–0507]

Determination That Halflytely and Bisacodyl Tablets Bowel Prep Kit (Containing Two Bisacodyl Delayed Release Tablets, 5 Milligrams) Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Halflytely and Bisacodyl Tablets Bowel Prep Kit (polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 milligrams (mg) (10-mg bisacodyl)) was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for bowel prep kits containing PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 mg.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

On September 23, 2010, FDA received a citizen petition (Docket No. FDA–2010–P–0507), submitted under § 10.30 (21 CFR 10.30), from Perrigo Company (Perrigo). The petition requests that the Agency determine whether Halflytely and Bisacodyl Tablets Bowel Prep Kit (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 mg) (Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl)), manufactured by Braintree Laboratories, Inc. (Braintree), was withdrawn from sale for reasons of safety or effectiveness.

Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) (NDA 21–551) was approved on September 24, 2007. Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) was indicated for the cleansing of the colon as preparation for colonoscopy in adults. Braintree informed FDA that it ceased to manufacture and market Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) as of July 17, 2010. The drug product was then moved to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records concerning the withdrawal of Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl). FDA has also independently evaluated relevant literature, data from clinical trials, and