comments to LeRoy Richardson, 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

Evaluation of Food Safety Programs—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Local and state food safety programs (FSPs) are on the frontline of foodborne disease prevention in the U.S. Through the Environmental Health Specialists Network (EHS-Net), CDC currently funds and works with local and state health departments in five states (California, New York, Minnesota, Rhode Island, and Tennessee) to: (1) Identify environmental antecedents (underlying factors) to illness and disease outbreaks; (2) translate findings into improved prevention efforts using a systems-based approach; (3) offer training opportunities to current and future environmental health specialists; and (4) strengthen collaboration among epidemiology, laboratory, and environmental health programs. This CDC program offers insights into the current status of FSPs among EHS-Net partners, but information is lacking on a national scale.

In the current economic milieu, food safety, along with other public health programs, is being eliminated due to funding reductions. Therefore, the CDC proposes to conduct the ''Evaluation of Food Safety Programs'' survey among a representative sample of local and state health departments implementing FSPs in the United States (U.S.).

The purpose of this evaluation of local and state FSPs is to collect descriptive data on the current status and activities, to describe changes in status and activities from 2007 to 2012, and to determine if there is a relationship between funding and status and activities. Data will be collected on food safety activities, workforce capacity and competency, financial resources, community health, and demographics of FSPs. Data collected will help CDC better understand the relationship between different levels of funding and FSP effectiveness in the U.S.

The evaluation survey will take approximately two hours to complete. The survey will be completed once by respondents either manually or electronically. The CDC is asking for this data collection burden to allow local and state health departments ample time to request and obtain the information they need from their various departments and units to complete the evaluation survey.

There are over 3,000 state and local health departments in the U.S. It is unknown how many state and local health departments will actually participate in the evaluation survey, as participation will be voluntary. Per year, the anticipated number of respondents for this survey is 190 health departments, and the requested number of burden hours is 380. The CDC is requesting OMB approval for two years.

Only local and state health departments implementing food safety programs in the U.S. will be eligible to participate in the survey. There will be no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Local health departments	Evaluation Survey (electronic)	138	1	2	276
	Evaluation Survey (paper-based)	35	1	2	70
State health departments	Evaluation Survey (electronic)	14	1	2	28
	Evaluation Survey (paper-based)	3	1	2	6
Total					380

Leroy Richardson,

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

[FR Doc. 2013–21543 Filed 9–4–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13–13AHL]

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 Leroy Richardson, 1600 Clifton Road, MS D–74, 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

Colorectal Cancer Screening Survey—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Unhealthy behaviors contribute to a significant public health gap in terms of eliminating preventable deaths. This gap disproportionately affects low-income, minority, uninsured or under-insured populations and stems in part from a failure to receive basic clinical preventative services such as cancer screening, as well as risk factors such as obesity, physical inactivity, excessive alcohol consumption and tobacco use. The challenge for public health is to identify the social interventions or mechanisms that might be effective in reaching members of the public who do not respond to traditional public health messages and interventions designed to support healthy behaviors. An improved understanding of the determinants of individual decision-making and behavior is needed to identify opportunities for strengthening public health interventions.

The Centers for Disease Control (CDC) plans to conduct a study to improve understanding of the reasons that individuals do not get screened for colorectal cancer (CRC). CRC is the second leading cause of cancer related death in the U.S., and screening for CRC is recommended for adults starting at age 50. Screening for CRC can prevent deaths by removing pre-cancerous polyps and finding cancer early when it is most treatable. However, as of 2008, only 62.9% of adults aged 50–75 years were screened as recommended.

CDC will request OMB approval to administer a survey to collect information on actual screening behavior, subjective and objective colon cancer risk perceptions, and barriers to screening. The survey is also designed to measure preferences for different characteristics of CRC screening tests. Information collection will involve a Web-based survey based on a conjoint analysis approach (also known as discrete choice experiment). The conjoint format presents respondents with choices between hypothetical CRC tests that vary along key attributes. The six attributes that will be assessed for CRC screening tests are: (1) What the test can find, (2) whether the test can remove cancer and polyps, (3) preparation before the test, (4) discomfort and activity limitations during and after the test, (5) how often an individual can take the test, and 6) cost of the test. Results will be analyzed to quantify the rate at which respondents are willing to trade-off one attribute for another and to rank the importance of attributes and changes in attribute levels.

The survey will also collect information to measure the impact of selected educational materials on opinions about CRC screening tests. Each respondent will be randomly assigned to one of three information treatments: (1) A control group that receives no additional information about CRC screening, (2) a treatment group that receives a ''No Excuses'' educational flyer designed to dispel many common reasons for not getting a colonoscopy, or (3) a treatment group that receives a two-page Fact Sheet about CRC and screening options. The flyer and fact sheet were developed in conjunction with CDC's Screen for Life program.

Information will be collected from a sample of 2,000 adults aged 52–75 through a Web-based survey administered by GfK Knowledge Networks (KN). The estimated burden per response is 20 minutes. Respondents will be randomly selected from the KN KnowledgePanel®. A pre-test of study procedures will be conducted prior to initiating the main study.

CDC is authorized to conduct this information collection under the Public Health Service Act (42 U.S.C. 241) Section 301. Results will be used to help CDC better understand public perceptions of screening tests and to improve rates of CRC screening among individuals at risk.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Pre-Test Participants	Email Invitation	43	1	2/60	1
	Survey of Preferences for Colorectal Cancer Screening.	30		20/60	10
Study Participants	Email Invitation	2,680	1	2/60	89
	Survey of Preferences for Colorectal Cancer Screening.	2,000	1	20/60	667
Total					767

Leroy A. Richardson,

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

[FR Doc. 2013–21604 Filed 9–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0477]

Center for Devices and Radiological Health: Draft Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Draft Standard Operating Procedure (SOP) for Level 1, Immediately in Effect (IIE) Guidance Documents on Premarket Data Issues. The SOP describes the Center for Devices and Radiological Health's (CDRH's or the Center's) draft process to clarify and more quickly inform stakeholders when CDRH has changed its expectations relating to, or otherwise has new scientific information that could affect, data submitted as part of an Investigational Device Exemption (IDE) or premarket submission, including a Premarket Notification 510(k), a Premarket Approval (PMA), or a Humanitarian Device Exemption (HDE) that needs to be disseminated in a timely manner.

DATES: The Agency encourages interested parties to submit information and either electronic or written comments by October 21, 2013.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document. Submit electronic comments on the draft SOP to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993–0002, 301–796–5678, *Philip.desjardins@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Task Force on the Utilization of Science in Regulatory Decision Making (the Task Force) published a Preliminary Report and Recommendations in August 2010. In the report, the Task Force noted that when new scientific information changes CDRH's regulatory thinking, it has been challenging for the Center to communicate the change and its basis to all affected parties in a meaningful and timely manner. The Task Force recommended that the Center make use of more rapid tools for broad communication on regulatory matters, including establishing a standard practice for communicating to all manufacturers of a particular group of devices for which the Center has changed its regulatory expectations on the basis of new scientific information.

Currently, manufacturers typically learn of changes CDRH implements regarding what data or how to gather specific data in support of an IDE or premarket submission, including a Premarket Notification 510(k), a PMA, or an HDE at the time of or soon after a decision is made through individual engagement with the Center, often not until after they have prepared that submission. Reviewers may implement these changes, such as requesting new clinical data or using a new test method, on a case-by-case basis, with immediate supervisory concurrence when it is necessary to protect the public health. For example, a reviewer may request that sponsors test their implantable device for durability because new data demonstrate that this type of device is prone to failure due to premature wear and tear of the technology. Although CDRH may issue a detailed guidance document, the document may not be published until a year or more after a Branch- or Division-level decision has been made to request the information because of the resource constraints in developing guidance documents.

CDRH believes that timely communication with industry about changes in premarket regulatory expectations is important. FDA's Good Guidance Practices regulation provides a mechanism for communicating and implementing certain changes in regulatory expectations quickly, without requiring prior public comment. Under 21 CFR 10.115(g)(2), FDA may issue a Level 1, IIE Guidance Document when prior public participation is not ''feasible or appropriate.'' Under these circumstances, CDRH intends to use the procedures described in § 10.115(g)(2) to issue guidance documents addressing changes in premarket regulatory expectations. CDRH has developed this SOP to facilitate issuance of such guidance documents.

On July 21, 2011 (76 FR 43693), CDRH issued a Standard Operating Procedure for ''Notice to Industry'' Letters, which outlined a similar process to clarify and quickly inform stakeholders of new CDRH expectations (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf*). After considering the comments received on that proposal, CDRH is now announcing a draft SOP that meets the Center's needs and addresses concerns raised regarding the original ''Notice to Industry'' proposal.

II. Electronic Access

Persons interested in obtaining a copy of the draft SOP may do so by using the Internet. The Draft Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues is available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf*. The draft SOP is also available from *http://www.regulations.gov* and can be located using the docket number found in brackets in the heading of this document.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: August 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21544 Filed 9–4–13; 8:45 am]

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