and text message surveys by feature phone (cell phones that do not have Web access), the outcomes of the surveys, and the value of the surveys. The universe for this study is English-speaking U.S. residents aged 18–65. The sample frame will consist of a national random digit dial sample of telephone numbers from a frame of known cell phone exchanges. Respondents reached on their cell phones will be asked to complete an initial CATI survey consisting of a short series of simple demographic questions, general health questions, and questions about tobacco and alcohol use. At the conclusion of this brief survey, respondents who have smartphones will be asked to participate in the feasibility study, which consists of a first follow-up survey and, a week later, a second follow-up survey. Those who agree will receive invitations to participate by text message, which will include a link to the survey. A sample of respondents who have feature phones will be asked to participate in a text message pilot, which also consists of a first follow-up survey and a second follow-up survey. Text message respondents will receive a text message inviting them to participate; respondents who opt in will receive text messages with one survey question at a time. Before initiating the feasibility study, CDC will conduct a brief pre-test of information collection forms and procedures.

This study will evaluate: (1) Response bias of a smartphone health survey by comparing data collected via CATI to data collected via smartphones/text messages, and data collected via smartphones to data collected via text messages, (2) relative cost-effectiveness of data collected via CATI to data collected via smartphones/text messages; (3) coverage bias associated with restricting the sample to smartphone users; and (4) the utility of smartphones for completing frequent, short interviews (e.g., diary studies to track activities or events).

OMB approval is requested for one year. Participation is voluntary. There are no costs to respondents other than their time. The total estimated annualized burden hours are 306.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Adults Aged 18 to 65, All cell phone users	Pre-test (CATI Screener/CATI Recruitment ...	20	1	8/60
	Screener/CATI Recruitment	1,990	1	1/60
	Initial CATI Survey	1,590	1	7/60
Adults Aged 18 to 65, Smartphone Users	First Web Survey Follow-up for Smartphone Users.	700	1	3/60
	Second Web Survey Follow-up for Smartphone Users.	595	1	3/60
Adults Aged 18 to 65, Non-smartphone Users	First Text Message Survey Follow-up for non-Smartphone Users.	200	1	3/60
	Second Text Message Survey Follow-up for non-Smartphone Users.	170	1	3/60

Ron A. Otten,

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

[FR Doc. 2013–08862 Filed 4–15–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0600]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing OMB # 0920–0600 (exp. 5/31/2013),—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the continuing effort to support domestic public health objectives for treatment of tuberculosis (TB), prevention of multi- drug resistance, and surveillance programs, CDC is requesting approval from the Office of Management and Budget to continue data collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacterium Drug Susceptibility Testing. This request includes (a) changing the title of the data collection to ''CDC Model Performance Evaluation (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing'' to reflect that nontuberculous mycobacteria are no longer included in the test package; (b) replacement of Laboratory Enrollment Form with a Participant Biosafety Compliance Letter of Agreement; (c) revision of the Pre-shipment Email; (d) addition of Instructions to Participants Letter; (e) revision of the MPEP M. tuberculosis Results Worksheet; (f) entering survey results online using a modified data collection instrument; (g) modification of Reminder Email; (h) modification of Reminder Telephone Script; and (i) modification of the Aggregate Report Letter.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium tuberculosis and

Non-tuberculous Mycobacterium Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

By providing an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis strains, laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) samples. The PE samples are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of tests performed annually.

There is no cost to respondents to participate other than their time. The total estimated annual burden hours are 156.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Domestic Laboratory	Participant Biosafety Compliance Letter of Agreement	93	2	5/60
MPEP	*Mycobacterium tuberculosis* Results Worksheet	93	2	30/60
	Online Survey Instrument	93	2	15/60

Ron A. Otten,

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

[FR Doc. 2013–08861 Filed 4–15–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0876]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Pretesting of Tobacco Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Pretesting of Tobacco Communications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 28, 2013, the Agency submitted a proposed collection of information entitled ''Pretesting of Tobacco Communications'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0674. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08860 Filed 4–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0391]

Generic Drug Facilities, Sites, and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the generic drug facility self-identification reporting period for fiscal year (FY) 2014 will begin on May 1, 2013, and close on June 1, 2013. Generic drug facilities, certain sites, and organizations identified in a generic drug submission are required by the Generic Drug User Fee Amendments of 2012 (GDUFA) to submit, update, or reconfirm identification information to FDA annually.

DATES: For FY 2014, identification information must be submitted, updated, or reconfirmed between May 1, 2013, and June 1, 2013.

ADDRESSES: Electronic tools for submitting the required information may be found on FDA's Web site at the following addresses:

- eSubmitter tool: *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm.*
- Structured Product Labeling (SPL) Xforms: *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm.*

Other applications are available commercially.

FOR FURTHER INFORMATION CONTACT: Jaewon Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 4145, Silver Spring, MD 20993, 301–796–6707, *AskGDUFA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: GDUFA (Pub. L. 112–144, Title III) was signed into law by the President on July 9, 2012, as part of the Food and Drug Administration Safety and Innovation Act. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to fund critical and measurable enhancements to FDA's generic drugs program. GDUFA will also significantly