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