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

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

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.


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” 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 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.


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/FDAsubmitter/ucm108165.htm
- Structured Product Labeling (SPL) Xforms: http://www.fda.gov/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
improve global supply chain transparency by requiring owners of facilities producing generic drug products and active pharmaceutical ingredients and certain other sites and organizations that support the manufacture or approval of these products to electronically self-identify with FDA and update that information annually.

Annual self-identification is required for two purposes. First, it is necessary to determine the universe of facilities required to pay user fees. Second, self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification enables quick, accurate, and reliable surveillance of generic drugs and facilitates inspections and compliance. Persons who self-identified for FY 2013 must self-identify again for FY 2014 between May 1, 2013, and June 1, 2013. Additional information including who is required to self-identify, how the information is submitted to FDA, the penalty for failure to self-identify, and the technical specifications are available on http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm.

Please note that registration and listing under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is a different process than self-identification under GDUFAC. Many persons will thus be required to submit information separately to the respective systems. Each system populates its own database to meet unique requirements and deadlines. Both, however, are built on the same platform and based on the same technical standards.


Leslie Kux, Assistant Commissioner for Policy.

[FR Doc. 2013–08867 Filed 4–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Research and Innovative Technology Administration


Nationwide Differential Global Positioning System (NDGPS)

AGENCY: Coast Guard, DHS and Research and Innovative Technology Administration (RITA), DOT.

ACTION: Notice; request for public comments.

SUMMARY: The Coast Guard and the Research and Innovative Technology Administration are analyzing the current and future user needs and requirements of the Nationwide Differential Global Positioning System (NDGPS). The NDGPS was designed to broadcast signals to improve the accuracy and integrity of the Global Positioning System (GPS) derived positions for surface transportation, as well as other civil, commercial, scientific, and homeland security applications. This analysis will be used to support future NDGPS investment decisions by the Department of Homeland Security and the Department of Transportation beyond fiscal year 2016. This notice seeks comments from Federal, state, and local agencies, as well as other interested members of the public regarding current and future usage of the NDGPS, the need to retain the NDGPS, the impact if NDGPS signals were not available, alternatives to the NDGPS, and alternative uses for the existing NDGPS infrastructure.

DATES: Comments and related material must reach the Docket Management Facility on or before July 15, 2013.

ADDRESSES: You may submit comments identified by docket number USCG–2013–0054 or RITA–2013–0001 using any one of the following methods: