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

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 GDUFA. 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.

Dated: April 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08806 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–0385]

Document to Support Submission of an Electronic Common Technical Document—Specifications for File Format Types Using Electronic Common Technical Document Specifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following document that supports making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications: ''Specifications for File Format Types Using eCTD Specification.''

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT: Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1161, ≤ Silver Spring, MD 20993, email: *virginia.hussong@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. Previously, formats for files contained within eCTD submissions were limited to those specified in the ''eCTD Backbone File Specification for Modules 2 through 5.3.2.2.'' However, as review tools and methods have changed and with the acceptance of advertising and promotional labeling in the eCTD format, it has become necessary to expand the range of file types accepted.

II. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: April 10, 2013.

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

[USCG–2013–0054; RITA–2013–0001]

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: