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]

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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: