

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](mailto: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/Development>

[ApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm](http://www.fda.gov/Drugs/Development/ApprovalProcess/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:

(1) *Federal eRulemaking Portal:*  
<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, contact LT Luke Byrd, Coast Guard, NDGPS Program Manager, telephone 202-372-1547 or email [Robert.l.byrd@uscg.mil](mailto:Robert.l.byrd@uscg.mil); or Timothy A. Klein, Research and Innovative Technology Administration, Senior Policy Advisor, telephone 202-366-0075 or email [NDGPS@dot.gov](mailto:NDGPS@dot.gov). If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Docket Operations, telephone 202-366-9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Public Participation**

You may submit comments and related material regarding this proposed policy. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

*Submitting comments:* If you submit a comment, please include the docket number for this notice (USCG-2013-0054 or RITA-2013-0001) and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and use "USCG-2013-0054" or "RITA-2013-0001" as your search term. Locate this notice in the results and click the corresponding "Comment Now" box to submit your comment. If you submit your comments by mail or hand delivery, submit them in an unbound

format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period.

*Viewing the comments:* To view comments, as well as documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov> and use "USCG-2013-0054" or "RITA-2013-0001" as your search term. Use the filters on the left side of the page to highlight "Public Submissions" or other document types. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy Act:* Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

##### **Background and Purpose**

The NDGPS augments GPS with an additional differential correction signal. Differential GPS (DGPS) receivers collect transmitted signals from GPS satellites in view, plus the NDGPS correction signals from a nearby NDGPS site. The correction signal improves the accuracy of the GPS position fix.

The NDGPS was developed by the Coast Guard in the 1990s to improve GPS-calculated positions for navigation, for positioning aids to navigation, in support of maritime safety requirements and to offset the error induced by the GPS Selective Availability<sup>1</sup> function at that time. The Coast Guard's authority to establish, maintain, and operate such

<sup>1</sup> Initially, high quality GPS signals were only available for military use. GPS signals available for civilian use were intentionally degraded out of concern that civilian GPS signals could be used to guide precision weapons. This degradation feature is known as Selective Availability. On May 1, 2000, President Clinton announced that the United States would stop using the Selective Availability feature. For more information on Selective Availability, visit the Coast Guard's Web site at <http://www.navcen.uscg.gov/?pageName=gpsSelectiveAvailability>.

aids to navigation is found in 14 U.S.C. 81.

In 1997, the Department of Transportation and Related Agencies Appropriations Act of 1998 (Pub. L. 105-66, section 346 (111 Stat. 1449)) authorized the implementation of the inland component of NDGPS. In 2006, RITA assumed the lead agency role for the inland NDGPS sites.

On August 1, 2007, RITA published a notice in the **Federal Register** announcing that it was assessing the user needs and systems requirements of the inland (terrestrial) component of the NDGPS (72 FR 42219). On April 18, 2008, based on RITA's assessment, DOT announced its approval of the continuation of inland NDGPS operations.

There are currently 86 NDGPS sites throughout the United States. The Coast Guard funds 49 NDGPS Maritime sites. DOT funds 29 NDGPS Inland sites. The remaining eight NDGPS sites are under the sponsorship of the U.S. Army Corps of Engineers (USACE), and these sites are not addressed in this notice. For more information on the NDGPS, visit the Coast Guard's Web site at <http://www.navcen.uscg.gov/?pageName=dgpsMain>. Additional information on the NDGPS is available in the 2012 Federal Radionavigation Plan, published by the Department of Defense, DHS, and DOT. A copy of the 2012 Federal Radionavigation Plan is available for viewing in the public docket for this notice.

DHS, through the Coast Guard, and DOT, through RITA, are analyzing the future requirements for the NDGPS to support investment decisions beyond fiscal year 2016. Future investment decisions may include: maintaining NDGPS as currently configured; decommissioning the entire NDGPS as currently configured; decommissioning a portion of the NDGPS and retaining select sites; or developing alternate uses for the NDGPS infrastructure. Contributing factors to these decisions are: (1) Coast Guard changes in policy to allow aids to navigation (ATON) to be positioned with a GPS receiver using Receiver Autonomous Integrity Monitoring (RAIM); (2) increased use of Wide Area Augmentation System (WAAS) in commercial maritime applications; (3) limited availability of consumer-grade NDGPS receivers; (4) no NDGPS mandatory carriage requirement on any vessel within U.S. territorial waters; (5) the May 1, 2000 Presidential Directive turning off GPS Selective Availability; (6) continuing GPS modernization; and (7) the Federal Railroad Administration's determination that NDGPS is not a

requirement for the successful implementation of Positive Train Control.

### Request for Comments

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.

We request comments from all interested parties to ensure that we identify the full range and significance of these issues. We specifically request comments regarding the following questions:

(1) To what extent do you use the NDGPS in its current form for positioning, navigation, and timing?

(2) What would be the impact on NDGPS users if the NDGPS were to be discontinued?

(3) If NDGPS were to be discontinued, what alternatives can be used to meet users' positioning, navigation, and timing requirements?

(4) What potential alternative uses exist for the existing NDGPS infrastructure?

After considering all comments, DHS and DOT will inform the public of the agreed course of action with respect to future investment in the NDGPS.

**Authority:** This notice is issued under the authority of 5 U.S.C. 552(a), 14 U.S.C. 81, and 49 U.S.C. 301 (Pub. L. 105-66, section 346).

Dated: April 8, 2013.

**Dana Goward,**

Director of Marine Transportation Systems,  
U.S. Coast Guard.

Dated: April 8, 2013.

**Gregory D. Winfree,**

Deputy Administrator, Research and  
Innovative Technology Administration.

[FR Doc. 2013-08844 Filed 4-15-13; 8:45 am]

**BILLING CODE 9110-04-P**

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R8-ES-2013-N031; 80221-1113-0000-C2]

#### Endangered and Threatened Wildlife and Plants; Revised Recovery Plan for Lost River Sucker and Shortnose Sucker

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of document availability.

**SUMMARY:** We, the Fish and Wildlife Service, announce the availability of the

final revised recovery plan for Lost River sucker (*Deltistes luxatus*) and shortnose sucker (*Chasmistes brevirostris*), two endangered fish species found in only a few lakes and reservoirs in the upper Klamath Basin and Lost River sub-basin in southern Oregon and northern California. The recovery plan includes recovery objectives and criteria, and specific actions necessary to achieve downlisting and delisting from the Federal List of Endangered and Threatened Wildlife and Plants. We revised this plan because a substantial amount of new information is available related to recovery of both species, making it appropriate to incorporate that new information into the recovery program.

**ADDRESSES:** You may obtain a copy of the revised recovery plan from our Web site at <http://www.fws.gov/endangered/species/recovery-plans.html>.

Alternatively, you may contact the Klamath Falls Fish and Wildlife Office, U.S. Fish and Wildlife Service, 1936 California Avenue, Klamath Falls, OR 97601 (telephone 541-885-8481).

**FOR FURTHER INFORMATION CONTACT:** Laurie Sada, Field Supervisor, at the above address or telephone number.

#### SUPPLEMENTARY INFORMATION:

##### Background

Recovery of endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of our endangered species program and the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). Recovery means improvement of the status of listed species to the point at which listing is no longer appropriate under the criteria specified in section 4(a)(1) of the Act. The Act requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species.

The Lost River sucker (*Deltistes luxatus*) and shortnose sucker (*Chasmistes brevirostris*) are two species of fish that inhabit a limited number of lakes in southern Oregon and northern California. We listed these species as endangered throughout their entire range under the Act on July 18, 1988 (53 FR 27130). The first recovery plan for the species was published on March 17, 1993 (USFWS 1993, pp. 1-108). However, since a substantial amount of additional information is now available, it is appropriate to revise the plan and incorporate this new information into the recovery program.

Section 4(f) of the Act requires us to provide an opportunity for public review and comment prior to finalization of recovery plans, including revisions to such plans. We made the draft of this revised recovery plan available for public comment from October 18, 2011 through December 19, 2011 (76 FR 64372). We considered all information we received during the public comment period and revised the recovery plan accordingly.

#### Species Information

Lost River and shortnose suckers are very similar in ecology. They both predominantly inhabit lake environments but also periodically utilize other aquatic habitats. Both species spawn during spring over gravel bottoms in tributary streams and rivers (Buettner and Scopettone 1990, pp. 19-20, 44-46). A relatively small, but significant, number of Lost River sucker also spawn over gravel bottoms at shoreline springs or upwellings along the margins of Upper Klamath Lake (Janney *et al.* 2009, pp. 8-9). Larvae spend little time in rivers or streams after hatching, drifting passively to downstream lakes within a few days (Cooperman and Markle 2003, p. 1138). Once in a lake environment, larvae move into shallow, vegetated areas along the shoreline. This vegetation provides cover from predators, protection from currents and turbulence, and food sources (Cooperman and Markle 2004, p. 365). Within one to two months, larvae become juveniles and begin to utilize non-vegetated, deeper off-shore areas (Burdick *et al.* 2008, p. 417). Adults occupy open water habitats throughout the year, except during spawning season, when they migrate to spawning areas. Individuals typically become reproductively mature at 4 to 7 years old, and can live for several decades.

The rationales for listing Lost River sucker and shortnose sucker were similar, and many of the same threats continue, such that both species remain in danger of extinction. Habitat loss, including restricted access to spawning and rearing habitat, severely impaired water quality, and increased rates of mortality resulting from entrainment in water management structures, were cited as causes for declines in populations prior to listing (53 FR 27130; July 18, 1988). Although the rate of habitat loss has slowed in recent years, and a significant amount of habitat restoration and screening of water diversion structures has occurred, large amounts of historical sucker habitat remain unavailable or significantly altered. In Upper Klamath