

ADDRESSES: The public meeting will be held at the National Aeronautics and Space Administration Headquarters Auditorium, 300 E Street SW., Washington, DC 20546. The visitor's entrance is on the West side of the building.

Submit presentations in response to Notice-MVC-2014-01 by any of the following methods:

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, GSA, at 202-501-0650 or email Edward.Loeb@gsa.gov. Please cite Notice-MVC-2014-01; Public Meeting—Expanded Reporting of Nonconforming Items.

SUPPLEMENTARY INFORMATION: DoD, GSA and NASA are interested in conducting a dialogue with experts and interested parties in Government and the private sector about expanded reporting of nonconforming items in the existing Government-Industry Data Exchange Program (GIDEP) operated by the Department of Defense. Expanded GIDEP reporting of nonconforming items is expected to mitigate the growing threat that counterfeit items pose and to reduce the risk of counterfeit items entering the supply chain.

Such expanded reporting would build on existing contractor inspection system requirements, utilizing existing terminology, and would add a requirement for contractors to report to the GIDEP database a counterfeit item, a suspect counterfeit item, or an item that contains a major or critical nonconformance that is a common item and that constitutes a quality escape that has resulted in the release of like nonconforming items to more than one customer. GIDEP has been in existence for over two decades and has a Web site at www.gidep.org.

Such expanded reporting of nonconforming items would partially implement section 818 of the National Defense Authorization Act for Fiscal Year 2012 and implement requirements of the Office of Federal Procurement Policy Policy Letter 91-3, entitled "Reporting Nonconforming Products," dated April 9, 1991.

Pre-Registration: The public is asked to pre-register by June 10, 2014, due to security and seating limitations. To pre-register, please send an email to Edward Loeb of the General Services Administration (GSA) at Edward.Loeb@gsa.gov. The pre-registration request should include the first and last name of the attendee(s), and, if applicable, company or organization name. Registration check-in will begin at 12:00 p.m., and the meeting will start at 1:00 p.m. and conclude by 5:00 p.m., eastern

standard time. Attendees must be prepared to present a form of government issued photo identification. Attendees are encouraged to arrive at least 30 minutes early to accommodate security procedures.

If you wish to make a presentation, please submit an electronic copy of your presentation (not greater than 19 MB) to Edward.Loeb@gsa.gov no later than June 12, 2014. When submitting presentations, provide presenter's name, organization affiliation, telephone number, and email address on the cover page. Please submit presentations only and cite "Public Meeting—Expanded Reporting of Nonconforming Items" in all correspondence related to the public meeting. There will be no transcription of the meeting. The submitted presentations will be the only record of the public meeting. All presentations received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. Time allocations for oral presentations will be limited to five minutes.

Meeting Accommodations: The public meeting is physically accessible to people with disabilities. Request for sign language interpretation or other auxiliary aids should be directed to Mr. Edward Loeb by June 10, 2014.

The TTY number for further information is: 1-800-877-8339. When the operator answers the call, let them know the agency is the General Services Administration; the point-of-contact is Mr. Edward Loeb.

Dated: May 12, 2014.

William Clark,

Acting Director, Office of Government-Wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0546]

Announcement of Center for Tobacco Products' Move to the Food and Drug Administration's White Oak Campus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Tobacco Products (CTP) will be moving its office from various Rockville, MD, locations to the

FDA White Oak campus in Silver Spring, MD. The move will commence on or about June 6, 2014, and will end approximately 3 weeks later, on or about June 22, 2014. During this time persons may continue to send applications and other submissions electronically via the eSubmitter tool and FDA Electronic Submissions Gateway to CTP for review, evaluation, or other handling. Persons should send submissions on paper or on electronic media (CD, DVD) to CTP's new mailing addresses once they take effect. CTP's new mailing addresses, including the dates they take effect, as well as other information concerning CTP's move to the FDA White Oak campus in Silver Spring, MD, will be provided on the FDA Web site at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/aboutthecenterfortobaccoproducts/ucm212531.htm>, as they become available. During the period required for relocation of files, equipment, and Agency personnel, CTP will make every effort to meet its review time frames and minimize any potential delay. Should delays affecting receipt and review of applications and other submissions occur, we intend to update the FDA Web site as needed.

FOR FURTHER INFORMATION CONTACT:

Janelle Barth, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-796-7320.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) as amended by the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31), CTP is responsible for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

In an effort to consolidate, FDA is moving CTP's offices from various Rockville, MD, locations to the FDA White Oak campus in Silver Spring, MD. The move will begin on or about June 6, 2014, and will end about 3 weeks later, on or about June 22, 2014. During this time, persons may continue to send applications and other submissions electronically via the eSubmitter tool and FDA Electronic Submissions Gateway (ESG) to CTP for review, evaluation, or other handling. Information about using the eSubmitter tool and ESG is available at <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForManufacturers/default.htm>. Persons should send

submissions on paper or on electronic media (CD, DVD) to CTP's new mailing addresses once they take effect. CTP's new mailing addresses, including the dates they take effect, as well as other information concerning CTP's move to the FDA White Oak campus in Silver Spring, MD, will be provided on the FDA Web site at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/aboutthecenterfortobaccoproducts/ucm212531.htm> as they become available.

During the period required for relocation of files, equipment, and Agency personnel, CTP will make every effort to meet its review time frames and minimize any potential delay. Should delays affecting receipt and review of applications and other submissions occur, we intend to update the FDA Web site as needed.

II. Comments

Persons who have questions or wish for further information concerning CTP's move to the FDA White Oak campus in Silver Spring, MD, may access the FDA Web site at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/aboutthecenterfortobaccoproducts/ucm212531.htm> for more information. CTP intends to update this Web site periodically.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0724]

Documents To Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised final versions of the following four documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD): “The eCTD Backbone Files Specification for Module 1,” version 2.3 (which includes the U.S. regional document type definition (DTD), version 3.3); “The Comprehensive Table

of Contents Headings and Hierarchy,” version 2.3; “Specifications for eCTD Validation Criteria,” version 3.1; and “Example Submissions using eCTD Backbone Files Specification for Module 1,” version 1.3. Technical files that support these documents are also available on the Agency Web site. FDA estimates it will be able to receive submissions using Module 1 Specifications 2.3 by the fourth quarter of calendar year 2014, and will give 30 days’ advance notice to industry.

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 the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002. 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: Constance Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1105, Silver Spring, MD 20993, 301-796-1065, email: constance.robinson@fda.hhs.gov; or Joseph Montgomery, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7328, Silver Spring, MD 20993-0002, 240-402-8125, email: joseph.montgomery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is a format for the transfer of regulatory information from the pharmaceutical industry to the FDA. It was developed by an expert working group of the International Conference on Harmonisation, and has been FDA's preferred format for electronic submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) since 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the current version of eCTD, it has become necessary to: (1) Update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, (2) clarify business rules for submission processing and review, (3) refine the characterization of promotional marketing and advertising material, and

(4) facilitate automated processing of submissions. FDA previously announced availability of final versions of technical documentation in a **Federal Register** notice dated August 26, 2013 (78 FR 52776).

The Agency revised the final documentation to accommodate the redesignation of section 503B as new section 503C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b as 353c). We removed references to 503B and 353b and replaced them with “Pre-Dissemination Review of Television Ad” because of the redesignation of section 503B as section 503C. We also changed references to DTD version 3.2 to version 3.3 in the Specifications for eCTD Validation Criteria. In addition, we revised the wording of eCTD validation error 2001 to reflect the changes. A full description of the changes is contained in the appendices of each document. The Agency is making available revised versions of the following documents:

- “The eCTD Backbone Files Specification for Module 1, version 2.3,” which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER (this document should be used in conjunction with the guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications”);
- “The Comprehensive Table of Contents Headings and Hierarchy,” version 2.3;
- “Specifications for eCTD Validation Criteria,” version 3.1; and
- “Example Submissions using eCTD Backbone Files Specification for Module 1,” version 1.3.

Supporting technical files are available on the Agency Web site.

FDA is not prepared at present to accept submissions using this new version of the eCTD Backbone Files Specification for Module 1, version 2.3, because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions using Module 1 Specifications 2.3 by the fourth quarter of calendar year 2014, and will give 30 days’ advance notice to industry.

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/>