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.

[FR Doc. 2014–11169 Filed 5–14–14; 8:45 am]

BILLING CODE 4160–01–P

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/*

ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11178 Filed 5–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 035

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (''FDA Recognized Consensus Standards''). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 035'' (''Recognition List Number: 035''), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VI for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 035'' to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149.

Submit electronic or written comments concerning this document or concerning recommendations for additional standards for recognition to the contact person (see **FOR FURTHER INFORMATION CONTACT**). This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*. See section V of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 035 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993–0002, 301–796–6287, *standards@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language and portable document format versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section V for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 035

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. We will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database, using the term ''Recognition List Number: 035'' to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. Radiology			
12–207		IEC 60601–2–33 Edition 3.0 2010–03, Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	Recognition restored with transition period.
12–208		IEC 60601–2–22 Third edition 2007–05 Medical electrical equipment—Part 2–22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment.	Recognition restored with transition period.