DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0724]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following draft versions of documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications entitled ''The eCTD Backbone Files Specification for Module 1, version 2.0'' (which includes the U.S. regional document type definition, version 3.0) and ''Comprehensive Table of Contents Headings and Hierarchy, version 2.0.'' Supporting technical files are also being made available on the Agency Web site. These draft documents represent FDA's major updates to Module 1 of the eCTD, which contains regional information.

DATES: Submit either electronic or written comments on the draft documents by December 27, 2011.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), 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 (CBER), 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.

Submit electronic comments on the draft documents to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, *Esub@fda.hhs.gov;* or Mary Padgett, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–0373, *mary.padgett@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. CDERCBER 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. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, to provide clarification of business rules for submission processing and review, to refine the characterization of promotional marketing and advertising material, and to facilitate automated processing of submissions. In preparation for the Module 1 update, FDA is making available for comment the following draft documents:

- ''The eCTD Backbone Files Specification for Module 1, version 2.0'' provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER. It should be used in conjunction with the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions,'' which will be revised as part of the implementation of the updated eCTD backbone files specification.
- ''The Comprehensive Table of Contents Headings and Hierarchy, version 2.0'' reflects updated headings that are specified in the draft document entitled ''The eCTD Backbone Files Specification for Module 1, version 2.0,'' as well as mappings to regulations and legislation.

Supporting technical files are also being made available on the Agency Web site.

The draft documents include the following changes:

- Providing for processing of bundled submissions (*e.g.,* a supplement can be applied to more than one new drug application or biologics license application),
- Providing detailed contact information so that companies can specify points of contacts to discuss technical matters that may arise with a submission,
- Clarifying headings, and
- Using attributes in place of certain headings to provide flexibility for future changes without revising the specification itself.

The draft documents contain complete lists of the changes to Module 1.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the draft documents. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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

Dated: October 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–27658 Filed 10–25–11; 8:45 am]

BILLING CODE 4160–01–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of ACHP Quarterly Business Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will meet Thursday, November 10, 2011. The meeting will be held at 8:30 a.m. in Room M09 in the Old Post Office Building, 1100 Pennsylvania Ave., NW., Washington, DC 20004.

The ACHP was established by the National Historic Preservation Act of 1966 (16 U.S.C. 470 *et seq.*) to advise the President and Congress on national historic preservation policy and to comment upon federal, federally assisted, and federally licensed undertakings having an effect upon properties listed in or eligible for