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

inclusion in the National Register of Historic Places. The ACHP's members are the Architect of the Capitol; the Secretaries of the Interior, Agriculture, Defense, Housing and Urban Development, Commerce, Education, Veterans Affairs, and Transportation; the Administrator of the General Services Administration; the Chairman of the National Trust for Historic Preservation; the President of the National Conference of State Historic Preservation Officers; a Governor; a Mayor; a Native American; and eight non-federal members appointed by the President.

Call to Order_8:30 a.m.
I. Chairman's Welcome
II. Presentation of Chairman's Award
III. Chairman's Report
IV. ACHP Management Issues
- A. Credentials Committee Report and Recommendations—Update
- B. Alumni Foundation Report
- C. ACHP FY 2012 Budget

V. Historic Preservation Policy and Programs
- A. Preservation Action Federal Preservation Task Force Report and Recommendations
- B. National Park Service ''Call to Action''
- C. National Trust for Historic Preservation's ''Preservation 10X'' and the ACHP
- D. White House American Latino Heritage Initiative
- E. Legislative Agenda
- F. Navy War of 1812 Initiative
- G. Rightsizing Task Force Report
- H. Sustainability Task Force Report
- I. Federal Preservation Funding for Disaster Recovery

VI. Section 106 Issues
- A. Section 3 Report Development
- B. Native American Traditional Cultural Landscapes Action Plan
- C. Department of Veterans Affairs Section 106 Issues
- D. Administration's Priority Projects—Report

VII. New Business
VIII. Adjourn

Note: The meetings of the ACHP are open to the public. If you need special accommodations due to a disability, please contact the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Room 803, Washington, DC, (202) 606–8503, at least seven (7) days prior to the meeting. For further information: Additional information concerning the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., #803, Washington, DC 20004.

Dated: October 19, 2011.

Reid Nelson,

Acting Executive Director.

[FR Doc. 2011–27533 Filed 10–25–11; 8:45 am]

BILLING CODE 4310–K6–M

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2011–0079]

Agency Information Collection Activities: Submission for Review; Information Collection Request for the Department of Homeland Security (DHS), Science and Technology, Biodefense Knowledge Center (BKC)

AGENCY: Science and Technology Directorate, DHS.

ACTION: 30-day Notice and request for comment.

SUMMARY: The Department of Homeland Security (DHS), Science & Technology (S&T) Directorate invites the general public to comment on data collection forms for the Biodefense Knowledge Center (BKC) program. BKC is responsible for coordinating the collection of Life Sciences Subject Matter Experts (SMEs) information with the Office of the Director of National Intelligence (ODNI), which operates under the authority of the National Security act of 1947, as amended by the Intelligence Reform and Terrorism Prevention Act of 2004. These authorities charge the ODNI with responsibility to coordinate and rationalize the activities of the Intelligence Community components. The SME information is necessary to understand who can provide scientific expertise for peer review of life science programs. In addition, the directory makes it easier to identify scientific specialty areas for which there is a shortage of Subject Matter Experts (SMEs) with appropriate security clearances.

The DHS invites interested persons to comment on the following form and instructions (hereinafter ''Forms Package'') for the S&T BKC: (1) Subject Matter Expert Registration Form (DHS FORM 10043 (2/08)). Interested persons may receive a copy of the Forms Package by contacting the DHS S&T PRA Coordinator. This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Comments are encouraged and will be accepted until November 25, 2011.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to: Desk Officer for the Department of Homeland Security, Science and Technology Directorate, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974. Please include docket number DHS–2011–0079 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: DHS S&T PRA Coordinator Millie Ives (202) 254–6828 (Not a toll free number).

SUPPLEMENTARY INFORMATION: The information is collected via the DHS S&T BKC secure Web site at *https://bkms.llnl.gov/sme.* The BKC Web site only employs secure web-based technology (*i.e.,* electronic registration form) to collect information from users to both reduce the burden and increase the efficiency of this collection.

The Department is committed to improving its information collection and urges all interested parties to suggest how these materials can further reduce burden while seeking necessary information under the Act.

DHS is particularly interested in comments that:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Suggest ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Suggest ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Renewal of information collection

(2) *Title of the Form/Collection:* Science and Technology, Biodefense Knowledge Center (BKC) program.

(3) *Agency Form Number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Department of Homeland Security, Science &