



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1309]

M8 Electronic Common Technical Document v4.0 Draft Implementation Guide v2.0; Electronic Common Technical Document v4.0 Implementation Package Draft Specification for Submission Formats v2.0; International Conference on Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled "M8 Electronic Common Technical Document (eCTD) v4.0 Draft Implementation Guide v2.0" (the M8 eCTD draft implementation guidance) and a related document entitled "eCTD v4.0 Implementation Package Draft Specification for Submission Formats v2.0" (the draft specifications document). The M8 eCTD draft implementation guidance and the draft specifications document were prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The M8 eCTD draft implementation guidance provides instructions for creating the eCTD v4.0 Health Level 7 Regulated Product Submission (RPS) message for Modules 2 through 5 of the eCTD. The draft specifications document

provides specifications for creating files for inclusion in the eCTD. These draft documents represent major updates to the eCTD specifications.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on these draft documents before it begins work on the final versions of the documents, submit either electronic or written comments on the draft documents by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft documents to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft documents may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance 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: Regarding the guidance: Jared Lantzy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1116, Silver Spring, MD 20993-0002, 301-796-0597; or Mark Gray, Center for

Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7217, Silver Spring, MD 20993-0002, 301-796-2081.

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1174, Silver Spring, MD 20993-0002, 301-796-8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The eight ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; and Swissmedic. The ICH Secretariat, which coordinates the preparation of documentation, is

provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization and the European Free Trade Area.

The eCTD is an ICH standard based on specifications developed by ICH and its member parties. The ICH M2 Expert Working Group has previously developed a list of requirements for input in the eCTD RPS Project. The list of requirements was last updated on November 11, 2010, and is available at http://estri.ich.org/ICH_eCTD_NMV_Requirements-V4-0.pdf (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register).

The ICH M8 Expert Working Group was formed in November 2010 to assume responsibility for the continued development of the next major version of the eCTD.

In February 2015, the ICH Steering Committee agreed that a draft guidance entitled "M8 eCTD v4.0 Draft Implementation Guide v2.0" and the related document entitled "eCTD v4.0 Implementation Package Draft Specification for Submission Formats v2.0" should be made available for public comment. These documents are the product of the M8 Expert Working Group. Comments about these draft documents will be considered by FDA and the M8 Expert Working Group.

Since adoption of the eCTD standard, the ICH Steering Committee has endorsed using the RPS Release 2 standard. A core feature of the RPS standard is the flexibility the message provides to enable future eCTD enhancements. The M8 eCTD draft implementation guidance provides instructions for creating the eCTD v4.0 RPS message for the ICH Modules 2 through 5

of the eCTD. The draft specifications document provides specifications for creating files for inclusion in the eCTD. These draft documents facilitate implementation of the eCTD v4.0 standard. The draft documents are being issued as a package that includes the draft ICH code list and the M8 schema files. In addition, the FDA regional/module 1 documents have been developed and are available at

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm309911.htm>.

The M8 eCTD draft implementation guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding these documents to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: April 21, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015-09646 Filed: 4/24/2015 08:45 am; Publication Date: 4/27/2015]