they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 24, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by March 25, 2020.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallet at artair.mallett@fda.hhs.gov or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://www.fda.gov/AboutFDA/AdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1006]

Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7).” FDA has identified certain submission types that warrant an exemption (Type III drug master files (DMFs)) or a long-term waiver (certain positron emission tomography (PET) drug products and certain Type II DMFs supporting PET drugs or noncommercial submissions or applications) from the requirement to submit to the Agency in electronic common technical document (eCTD) format. In addition, this guidance outlines certain circumstances where FDA may determine that a short-term waiver from eCTD submission requirements could be granted. This guidance finalizes the revised draft guidance of the same title issued in July 2019 and replaces the final guidance issued in January 2019 (Revision 6).


ADDRESSES: You may submit either electronic or written comments on Agency guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made publicly available, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2014–N–1006 for “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7).” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the
heading of this document, into the “Search” box and follow the prompts
and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR
10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division
of Drug Information, Center for Drug Evaluation and Research, Food and
Drug Administration, 10001 New Hampshire Ave., Hildandale Building,
4th Floor, Silver Spring, MD 20993–0002; or to 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 that office in processing your
requests. See the SUPPLEMENTARY INFORMATION section for electronic
access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Dorothy West, Center for Drug Evaluation and Research, Food and
Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6332,
Silver Spring, MD 20993–0002, 301–796–0164; or Stephen Ripley, Center for
Biologics Evaluation and Research, Food and Drug Administration, 10903
New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002,

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled
"Providing Regulatory Submissions in Electronic Format—Certain Human
Pharmaceutical Product Applications and Related Submissions Using the
eCTD Specifications (Revision 7)." This guidance provides information
regarding submission types that warrant an exemption or long-term waiver from
Agency eCTD requirements. In addition, this guidance outlines certain
circumstances where FDA will consider granting short-term waivers from eCTD
submission requirements. This guidance is intended to address current concerns
raised with FDA regarding the burden of complying with eCTD submission
requirements, which could have unintended public health consequences.

This guidance finalizes the draft guidance entitled "Providing Regulatory
Submissions in Electronic Format—Certain Human Pharmaceutical Product
Applications and Related Submissions Using the Electronic Common Technical
Document Specifications (Revision 7)" issued on July 16, 2019 (84 FR 33949).
The Agency received comments on the draft guidance requesting that FDA
clarify certain requirements relating to Type III DMF submissions. The Agency
considered these comments and made technical and editorial changes for
clarity, where appropriate. For example, "noncommercial products" was
changed to "noncommercial INDs" to clarify the type of submissions
referred in that section of the guidance. In addition, the FDA
Electronic Submissions Gateway (ESG) waiver request submission option has
been removed to avoid confusion when selecting from the ESG drop-down
options.

This guidance is being issued consistent with FDA’s good guidance
practices regulation (21 CFR 10.115). The guidance represents the current
thinking of FDA on "Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD
Specifications (Revision 7)."

FDA guidances ordinarily contain standard language explaining that
guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are
cited. FDA is not including this standard language in this guidance
because this guidance contains binding provisions. In section 745A(a) of the
Congress granted explicit authorization to FDA to specify in guidance the format
for the electronic submissions required under that section and required that
FDA “shall” issue such guidance.

Accordingly, this guidance explains such requirements under section
745A(a) of the FD&C Act, indicated by the use of the words must or required,
and therefore is not subject to the usual restrictions in FDA’s good guidance
practice regulations, such as the requirement that guidances not establish
legally enforceable responsibilities. See e.g., 21 CFR 10.115(d).

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information
found in FDA regulations. These collections of information are subject to
review by the Office of Management and Budget (OMB) under the Paperwork
Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in
21 CFR part 312 have been approved under OMB control number 0910–0014; the
collections of information in 21 CFR part 314 have been approved under
OMB control number 0910–0001; and the collections of information in 21 CFR
part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://
www.fda.gov/drugs/guidance-compliance- regulatory-information/
guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-
biochemicals-guidances, or https://
www.regulations.gov.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2020–03522 Filed 2–21–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Common Technical Document v4.0 Technical
Conformance Guide: Food and Drug Administration Electronic
Common Technical Document v4.0 Module 1 Implementation Package; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting comment on the draft Electronic Common Technical Document (eCTD) v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package. The eCTD v4.0 Technical Conformance Guide will provide specifications, recommendations, and general considerations on how to submit eCTD v4.0-based electronic submissions to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) using the International Council for Harmonisation eCTD v4.0 Implementation Package and the FDA eCTD v4.0 Module 1 Implementation Package. The Agency is seeking comment on the eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package for the accuracy, suitability, and appropriateness of these specifications for the submission of eCTD v4.0 submissions. These versions of the documents are not for implementation.