



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 This guidance finalizes the revised draft guidance of the same title issued in July 2019 and replaces the final guidance issued in January 2019 (Revision 6).

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 available to the public, 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., Hillandale 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, 240-402-7911.

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 referenced 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 Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379k-1(a)), 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-](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances)

[biologics/biologics-guidances](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances), or <https://www.regulations.gov>.

Dated: February 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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