Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2018
Electronic Submissions
Revision 5

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RELATED DOCUMENTS

Technical specifications associated with this guidance are provided as separate documents and are updated periodically. Documents cited within this guidance are provided at the end of this document.

For a complete listing of all documents and supportive files needed in order to submit electronically, refer to the eCTD web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

REVISION HISTORY

DATE	SUMMARY OF REVISIONS
April 2017	**Update to Guidance** Section I. Introduction • Paragraph added describing rationale for changing timetable for required master file submissions in eCTD from 24 months to 36 months. Section III.B. Timetable for Implementation of Electronic Submission Requirements • Updated to reflect that the requirement for master files to be filed electronically takes place 36 months after May 5, 2015. • Example of timetable updated to reflect actual timetable for the implementation of the electronic submissions requirement.
April 2018	**Update to Guidance** Section I. Introduction • Paragraph added describing rationale for extending timetable for Type III drug master file submissions in eCTD for an additional 12 months. Section III.A Types of Submissions That Must Adhere to the Electronic Submission Requirement Described in This Guidance • Revised paragraph to reflect change in nomenclature of "biologic product files (BPFs)" to "other master files relevant to a biological product." Section III.B. Timetable for Implementation of Electronic Submission Requirements • Updated to reflect that the requirement for Type III drug master files to be filed electronically takes place 48 months after May 5, 2015. • Example of timetable updated to reflect actual timetable for the implementation of the electronic submissions requirement.

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I. INTRODUCTION

Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), at least 24 months after the issuance of a final guidance document in which the Food and Drug Administration (FDA) has specified the electronic format for submitting submission types to the Agency, such content must be submitted electronically and in the format specified by FDA.[3] This guidance and the technical specification documents it incorporates by reference[4] describe how sponsors and applicants must organize the content that they submit to the Agency electronically for all submission types under section 745A(a) of the FD&C Act. In addition to this guidance and existing technical specification documents, further and more detailed technical instructions are included in a separate eCTD technical conformance guide.

This guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act for the electronic format of the content submitted in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). See section III.A of this document for more information regarding required submission types. Submissions that are not submitted electronically and electronic submissions that are not in a format that FDA can process, review, and archive will not be filed or received, unless exempted from the electronic submission requirements.

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[1] The term *human pharmaceutical product*, as used in this guidance, includes any product intended for human use that meets the definition of drug and does not also meet the definition of *device* under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including both drugs approved under the FD&C Act and biological products approved under the Public Health Service Act.

[2] This guidance has been prepared by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2017-D-6821 (available at https://www.regulations.gov/docket?D=FDA-2017-D-6821) (see the instructions for submitting comments in the docket).

[3] For additional information on how FDA interprets and intends to implement the electronic submission requirements of section 745A(a) of the FD&C Act, please see the guidance for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.* We update guidances periodically. For the most recent version of a guidance, see FDA's web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[4] For instance, to reflect the evolving nature of the technology and the experience of those using this technology, the Electronic Common Technical Document (eCTD) technical specifications are being provided as separate documents that are incorporated by reference into this guidance. These associated specifications will be updated periodically. To make sure you have the most recent version of related technical specifications (CDER and CBER), check the eCTD web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

The version of this guidance published on May 5, 2015 provided a timetable of 24 months after issuance of the final guidance for the initial implementation of the electronic submission requirement for NDAs, ANDAs, BLAs, and master files, and 36 months for commercial INDs. The timetable indicated that NDAs, BLAs, ANDAs, and master files were to be submitted electronically in eCTD format starting on May 5, 2017 (May 5, 2018 for commercial INDs). FDA determined, in response to industry comments and internal review, that it was appropriate to extend the required date to submit master files in electronic eCTD format by 1 year to May 5, 2018. Among other factors, FDA recognized that there were challenges with submission of master files in eCTD format, and eCTD uptake data for master files indicated that adhering to the May 5, 2017 date could have led to high rejection rates of master files and thus slower FDA review processes, and, therefore, potential unnecessary delay in the review of some drug applications.

Since the publication of the most recent revision, FDA has determined that application of the electronic submission requirement to Type III drug master files (DMFs) on May 5, 2018 could lead to high rejection rates of these submissions. Further, because Type III DMFs typically provide information regarding packaging or packaging materials in support of NDAs, ANDAs, or BLAs, should submitters choose not to submit or to no longer support existing Type III DMFs, this could lead to drug supply interruptions. Finally, only a small portion of Type III DMFs submitted to the Agency require assessment by FDA staff in support of a marketing application; in most cases, the information needed to support approval is already present in the marketing application. Given this, the burden on the Agency of allowing non-eCTD submissions for Type III DMFs during this interim period is expected to be low. FDA continues to recommend use of the eCTD format for Type III DMFs, but the Agency is issuing a revision to this guidance to extend the implementation date for Type III DMFs until May 5, 2019.

II. BACKGROUND

In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements in guidance. Accordingly, as indicated by the use of the words *must* or *required*, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d); see also the guidance for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (745A(a) Implementation Guidance)).

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidance documents should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance document because it is not an accurate description of all the effects of this guidance document. Insofar as this document specifies the format for electronic submissions, or provides "criteria for . . . exemptions" under section 745A(a) of the FD&C Act, it will have binding effect.

III. REQUIREMENT TO SUBMIT ELECTRONICALLY UNDER THIS GUIDANCE

Twenty-four (24) months after this guidance document had originally been published on May 5, 2015, sponsors and applicants were required to submit certain types of submissions in an electronic format specified in that guidance document. In other words, such submissions had to be consistent with the requirements set forth below.

A. Types of Submissions That Must Adhere to the Electronic Submission Requirement Described in This Guidance Document

Section 745A(a) of the FD&C Act applies to submissions under section 505(b), (i), or (j) of the FD&C Act and under section 351(a) or (k) of the Public Health Service (PHS) Act. These include the following submission types:

- Certain investigational new drug applications (INDs)[5,6]
- New drug applications (NDAs)
- Abbreviated new drug applications (ANDAs)
- Certain biologics license applications (BLAs)[7,8]

Section 745A(a) also applies to all subsequent submissions, including amendments, supplements, and reports, to the submission types identified above.

FDA considers master files to be submissions to an NDA, ANDA, BLA, or IND, and therefore to fall within the scope of requirements set forth in section 745A(a). These include new drug master files (DMFs) (21 CFR 314.420) and other master files relevant to a biological product (21 CFR 601.51), and any amendments to or annual reports on previously submitted DMFs or other master files relevant to a biological product. This guidance also applies to submissions for drug/device combination products filed pursuant to section 505 of the FD&C Act or subsection (a) or (k) of section 351 of the PHS Act.

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[5] This guidance is not applicable to INDs for devices that are regulated by CBER as biological products under section 351 of the PHS Act and that also require the submission of an IND prior to the submission of a BLA. Although a discussion of which devices CBER regulates as biological products is outside the scope of this guidance, as a general matter, this category of INDs would include investigational devices that are used to screen blood donors for certain transfusion-transmissible diseases and to test human cells, tissues, or cellular or tissue-based products (HCT/Ps) to make a donor-eligibility determination. These submissions are subject to the requirements under section 745A(b). See the final guidance *eCopy Program for Medical Device Submissions*, which implements the electronic copy provisions of section 745A(b) for medical device submissions to FDA.

[6] This guidance is not applicable to noncommercial INDs.

[7] This guidance is not applicable to those devices that are regulated by CBER as biological products under section 351 of the PHS Act, including those that do not require the submission of an IND prior to the submission of a BLA. Although a discussion of which devices CBER regulates as biological products under section 351 of the PHS Act is outside the scope of this guidance, as a general matter, this category would include those reagents used in determining donor/recipient compatibility in transfusion medicine. These submissions are subject to the requirements under section 745A(b). See the final guidance *eCopy Program for Medical Device Submissions*.

[8] Specifically, this guidance is not applicable to submissions for blood and blood components, including Source Plasma.

A submission that is not in the electronic format(s) described in this guidance document will not be filed or received, unless it has been exempted from the electronic submission requirements (see section III.C) with respect to that submission.

Under section 745A(a)(3) of the FD&C Act, the electronic submission requirements do not apply to submissions described in section 561 of the FD&C Act. FDA will continue to accept submissions under section 561 in alternative formats.

B. Timetable for Implementation of Electronic Submission Requirements

The requirement to submit NDAs, ANDAs, and BLAs electronically became effective 24 months after May 5, 2015, the original date of finalization of this guidance (Revision 3). The requirement for INDs and master files, other than Type III DMFs, to be filed electronically is effective 36 months after May 5, 2015 (May 5, 2018). For Type III DMFs, the requirement is effective 48 months after May 5, 2015 (May 5, 2019). For all of these submission types, you must electronically submit any amendments, supplements, and reports, even if the original submission was submitted to FDA prior to implementation of the electronic submission requirements.

The timetable for the initial implementation of the electronic submission requirement is summarized in Table 1 below.

On May 5, 2015, FDA published the final "Guidance on Providing Regulatory Submissions in Electronic Format -- Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications." Submission types NDA, ANDA and BLA must be submitted in eCTD format beginning May 5, 2017. IND submissions and master files must be submitted in eCTD format beginning May 5, 2018 (for Type III DMFs, May 5, 2019).

Table 1: Timetable for the Initial Implementation of the Electronic Submission Requirement

Submission Type	Final eCTD Guidance Published to FDA Web site (yyyy-mm-dd)	Date Requirement Begins (yyyy-mm-dd)
NDA ANDA BLA	2015-05-05	2017-05-05
Commercial IND Master files other than Type III DMFs	2015-05-05	2018-05-05
Type III DMFs	2015-05-05	2019-05-05

Additional information regarding submissions pertaining to promotional materials made to the Office of Prescription Drug Promotion in CDER and to the Advertising and Promotional Labeling Branch in CBER will be described in a separate guidance. Refer to that guidance for the timetable for implementation of those submissions in electronic format.

C. Types of Submissions That Are Exempted From the Electronic Submission Requirement Described in This Guidance Document

Section 745A(a) allows FDA to establish exemptions from the electronic submission requirements. Accordingly, FDA has exempted all submissions regarding noncommercial INDs from the requirements under section 745A(a).[9] For purposes of this guidance, the term *noncommercial products* refers to products that are not intended to be distributed commercially and includes investigator-sponsored INDs and expanded access INDs (e.g., emergency use INDs and treatment INDs).

Although these submissions will be exempt, FDA also accepts their submission electronically as described in this guidance document.

D. The eCTD Specifications

You must submit electronic submissions using the version of eCTD currently supported by FDA. The version of eCTD currently supported is specified in the Data Standards Catalog (available at http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM340684.xls) and is further described in the following technical specification documents:

- ICH[10] *Electronic Common Technical Document Specification*
- ICH *eCTD Backbone File Specification for Study Tagging Files*
- FDA *eCTD Backbone Files Specification for Module 1*

Additional technical specification documents are cited throughout this document. For a complete listing of required technical supportive files (e.g., stylesheets and valid values) that you will need in order to submit in the eCTD format, refer to the eCTD web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

E. Pre-Submission Considerations

Before making the first electronic submission to an application, you must obtain a pre-assigned application number by contacting the appropriate Center. Information regarding how to obtain a pre-assigned application number may be found on FDA's eCTD web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

[9] See 745A(a) Implementation Guidance, section III.B.
[10] International Council for Harmonization.

F. Submission Structure: Granularity, Files, and Folders

Document granularity, or the level for which the submission content is broken out into separate files, must be consistent with the FDA guidance for industry M4 Granularity Annex, *Granularity Document — Annex to M4: Organization of the CTD*, unless otherwise specified in the ICH M2 technical specification e*CTD IWG Question and Answer and Specification Change Request Document*.

With a few exceptions, the eCTD specification maps Common Technical Document (CTD) headings to Extensible Markup Language (XML) elements.[11] The specification indicates that each element (heading) is optional and that multiple document references (eCTD leaf elements) can be created under each heading.

You must also follow the FDA eCTD technical specification *Table of Contents Headings and Hierarchy* for the comprehensive listing of headings and hierarchy and a section mapping the headings to their respective regulations. Because this is a comprehensive listing, not all headings are applicable to all submissions or submission types.

Files pertaining to each module must be placed in the appropriate folder (e.g., m1 – m5). The terms *folder* and *subfolder*, as used in this guidance, are intended to be synonymous with *directory* and *subdirectory*. The main submission, regional administrative folders, and certain subfolders must have specific names.

You must use only letters, numbers, hyphens, or underscores in the folder and file names and not blank spaces or special characters. When naming folders and files, the length of the entire path must not exceed 150 characters. Empty folders and files must not be included in the submission.

All documents in the electronic submission must be placed in a main submission folder and named using a four-digit sequence number (which you must specify) that is unique within the application. The eCTD backbone file for modules 2 to 5 (*index.xml*) for the submission must be placed in this folder along with the checksum file for the eCTD backbone file (*index-md5.txt*). Numbering for each subsequent submission to the same application is described in the FDA technical specification *eCTD Backbone Files Specification for Module 1* (see section III.D). Sequence numbers are used to differentiate between submissions within the same application and need not correspond to the order in which they are received by FDA. It is not necessary for sequence numbers and IND serial numbers to match for submissions to an IND.

Subfolders within each module are required to organize files in a submission. These subfolders must be placed in the sequence number folder. Empty subfolders must not be included. The *util* subfolder is required to organize supporting eCTD technical files in the submission, as described in the ICH M2 technical specification *Electronic Common Technical Document Specification*

[11] For example, in Module 3, lower level headings subordinate to 3.2.P.2 (e.g., 3.2.P.2.1, 3.2.P.2.1.1) are not mapped to an XML element. Consequently, leaf element files relating to, for example, 3.2.P.2.1, 3.2.P.2.1.1, either must be submitted as multiple leafs under the parent 3.2.P.2 element (heading) or combined into larger files and submitted at the 3.2.P.2 heading level.

(see section III.D). Other specific folder names that are compliant with the eCTD version 3.2.2 format can be found in the same document.

G. File Formats and Versions

Files within an eCTD submission must adhere to the formats and versions specified in the associated FDA technical specification *Specifications for File Format Types Using eCTD Specifications*. Portable Document Format (PDF) files submitted must adhere to the FDA technical specification *Portable Document Format (PDF) Specifications*.

H. Document Lifecycle

If a document replaces a document previously submitted with an eCTD backbone file within the same application, you must use the eCTD *replace* operation to indicate this, rather than submitting the file as *new*. You must not indicate that files are new if they are in fact replacing files already submitted. If you intend to remove a file, you must use the *delete* operation. For instructions, see the ICH M2 technical specification *Electronic Common Technical Document Specification* (see section III.D).

I. Summary of Clinical Efficacy and Summary of Clinical Safety

When submitting a Summary of Clinical Efficacy and/or Summary of Clinical Safety, the location of these documents within the eCTD must adhere to the FDA guidance for industry *Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.*

J. Datasets and Study Information

Datasets must only be provided in modules 3, 4, or 5 and not in modules 1 or 2. When providing study information in either module 4 or 5, you must include the Study Tagging File (STF) described in the associated ICH M2 technical specification *eCTD Backbone File Specification for Study Tagging Files* (see section III.D). Datasets must be referenced in an STF using the appropriate STF *file-tag* describing the document's contents.

For further information regarding the submission of study data, see FDA guidance for industry *Providing Regulatory Submissions in Electronic Format — Standardized Study Data*.

K. Transmitting Electronic Submissions

The FDA Electronic Submissions Gateway (ESG)[12] enables the secure submission of regulatory information for review and is our preferred method of transmission. For all submissions that are 10 gigabytes (GB) or smaller, you must use the FDA ESG.

For submissions that are greater than 10 GB, refer to the FDA technical specification

[12] Additional information concerning the FDA ESG is available at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

Specification for Transmitting Electronic Submissions using eCTD Specifications.

L. FDA Forms

Electronic submissions must include only FDA fillable forms (e.g., 1571 or 356h) and electronic signatures to enable automated processing of the submission. The FDA forms are available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm. Scanned images of FDA forms will not be accepted.

M. Restrictions on Submission of Paper Copies

When submitting in eCTD format, paper copies of the application, including review copies and desk copies in paper, must not be submitted. The only exception to this is the submission of paper copies of meeting briefing materials, when requested, as described in the FDA guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants.*

N. Receipt Date

The receipt date for an electronic submission will be determined only after the submission has passed a technical validation check to ensure that it can be opened, processed, and archived. The submitter is responsible for monitoring their receipt pathway to determine whether a submission has been rejected. Additional information on the validation of electronic submissions is available in the FDA technical specification *Specifications for eCTD Validation Criteria*.

Additional information on receipt dates for electronic submissions is available in the FDA guidance for industry *Providing Regulatory Submissions in Electronic Format — Receipt Dates*.

Contact Information

For questions related to providing electronic submissions according to the recommendations in this guidance, you should contact the Center electronic submission coordinator at esub@fda.hhs.gov for submissions to CDER and esubprep@fda.hhs.gov for submissions to CBER. Specific questions pertaining to the content of applications should be directed to the appropriate review division or office.

TECHNICAL SPECIFICATION DOCUMENTS INCORPORATED BY REFERENCE

The following are technical specification documents incorporated by reference into this guidance (see section I). Documents are listed in order of first appearance in this guidance.

For a complete listing of technical supportive files that you will need in order to submit in eCTD format, refer to the eCTD web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

1. ICH M2 technical specification, *Electronic Common Technical Document Specification* (accessible at http://estri.ich.org/eCTD/index.htm)

2. ICH M2 technical specification, *The eCTD Backbone File Specification for Study Tagging Files* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirement s/ElectronicSubmissions/ucm153574.htm)

3. FDA technical specification, *eCTD Backbone Files Specification for Module 1* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirement s/ElectronicSubmissions/ucm153574.htm)

4. FDA guidance for industry, ICH M4 Granularity Annex, *Granularity Document — Annex to M4: Organization of the CTD* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirement s/ElectronicSubmissions/ucm153574.htm)

5. ICH M2 technical specification, *eCTD IWG Question and Answer and Specification Change Request Document* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirement s/ElectronicSubmissions/ucm153574.htm)

6. FDA technical specification, FDA eCTD *Table of Contents Headings and Hierarchy* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirement s/ElectronicSubmissions/ucm153574.htm)

7. FDA technical specification, *Specifications for File Format Types Using eCTD Specifications* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirement s/ElectronicSubmissions/ucm153574.htm)

8. FDA technical specification, *FDA Portable Document Format (PDF) Specifications* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm)

9. FDA guidance for industry, *Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm)

10. FDA technical specification, Transmission Specifications, *Specification for Transmitting Electronic Submissions Using eCTD Specifications* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm)

11. FDA technical specification, eCTD Validation Specifications web page, *Specifications for eCTD Validation Criteria* (accessible at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm)

RELATED REFERENCES

1. FDA guidance for industry, *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (accessible at http://www.fda.gov/downloads/Drugs/Guidances/UCM384686.pdf)

2. FDA guidance for industry, *Providing Regulatory Submissions in Electronic Format — Standardized Study Data* (accessible at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm)

3. FDA guidance for industry, *Formal Meetings Between the FDA and Sponsors or Applicants* (accessible at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm)

4. FDA guidance for industry, *Providing Regulatory Submissions in Electronic Format — Receipt Dates* (accessible at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072385.pdf)