POLICY AND PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

Requesting and Accepting File Formats Outside of the eCTD File Format Specifications for CDER Applications

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PURPOSE

This MAPP clarifies CDER's policy and procedures for requesting and accepting electronic material in formats outside the Electronic Common Technical Document (eCTD) file format specifications.

Note: This is not related to the process for requesting an eCTD waiver (i.e., submitting outside of the eCTD format) outlined in the referenced guidance on *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications;* the eCTD Waiver Committee web page.

BACKGROUND

Agency Guidance identifies the electronic formats that are considered acceptable for submitting materials in an electronic format. Occasionally, a submitter may wish to submit, or the Agency may request to receive, material in a file format that is not listed in the eCTD File Format Specification.

This MAPP clarifies the policy and procedures in CDER for requesting and accepting file formats that are not listed in the eCTD File Format Specifications. For purposes of this MAPP, file format is same as file extension.

POLICY

1. CDER discourages the submission of material in electronic formats that are not archivable as records, as described by law, regulation, or guidance.

2. In cases in which materials are submitted in an format that is not archivable (per NARA) the document must be accompanied by an archivable version (refer to the Specifications for File Format Types Using eCTD Specifications) containing the same information to serve as the record.

3. If a sponsor or applicant offers to provide electronic material requiring the installation of hardware or software on any component of the FDA information technology infrastructure, or if the use of the material requires Office of Business Informatics (OBI) staff support beyond what is needed for the electronic submission described in the guidance, advance approval from OBI is required. If approved, the CDER staff requesting alternative support must follow all applicable Office of Information Management Technology (OIMT) [1]guidelines governing the installation of hardware or software on the FDA information technology infrastructure.

RESPONSIBILITIES

Office of Business Informatics (OBI) Director or Designee:

- Identifies staff to serve as the Director of the Division of Data Management Services & Solutions (DDMSS).

Office of Strategic Programs (OSP)

- Manages the CDER Data Standards Operational Subcommittee

CDER Data Standards Operational Subcommittee (OpSC)

Ensures CDER's changes to data standards are communicated across CDER and CBER. CDER's OpSC is a subcommittee of the Data Standards Governance Board (DSDG) (see MAPP 7610.7, CDER Data Standards Program).

Division of Data Management Services and Solutions (DDMSS) Director:

- Identifies staff to serve as electronic submission coordinator.
- Ensures agreements between reviewers and sponsors or applicants for electronic material is consistent with CDER policy.

[1] OIMT is a suboffice in the Office of Digital Transformation (ODT) agency level and located within Office of the Commissioner (OC)

- Reviews proposals forwarded by the review organization.
- Determines if resources are available to support the electronic material.
- Negotiates with the review organization, to determine the appropriate level of support to be provided.
- Provides the review organization with technical advice on the acceptance of the proposed electronic material. Provides this response at least 15 business days prior to the proposed submission date of the electronic material.

The Electronic Submission Coordinator:

- Monitors the esub@fda.hhs.gov email account.
- Provides technical advice on industry requests to accept file formats outside of the eCTD File Format Specification.
- When unable to accept the request for accepting non-archivable electronic materials, collaborates with the CDER division reviewing the application to identify alternative methods for the receipt of the materials.
- Consults with OIMT when necessary.

The CDER organizations reviewing drug applications:

- When a new file format is required, provide justification to OBI.
- If OBI support is desired, request the support at least 30 days prior to the proposed submission date of the electronic material.
- Submit requests for OBI support to the esub@fda.hhs.gov email account.
- If it is anticipated the request of non-archivable electronic material will be made in an industry meeting, ensure the appropriate OBI/DDMMS staff are consulted prior to finalizing the decision.

PROCEDURES

1. Requests for advice on asking sponsors to submit file types not referenced in the *eCTD File Format Specifications* are sent by the CDER Division reviewing applications to the electronic submission coordinator at esub@fda.hhs.gov.

2. The electronic submission coordinator, or designee, analyzes the request and gives technical advice.

3. If the review organization expects a recurring need for a new file format, the initiating review organization collaborates with other relevant parties to agree upon the new file format.

4. The initiating review organization presents the agreed upon recommendation(s) for a new file format, with a justification, to OBI

(eSub) for consideration to include in the *eCTD File Format Specifications*.

5. OBI reviews the proposed addition to the *eCTD File Format Specifications* during eCTD Management meetings. If approved, the proposed addition is taken to the CDER Data Standards Operational Subcommittee, to ensure the proposed change is communicated to and voted by review offices.

REFERENCES

- The Federal Food Drug and Cosmetic Act, 2014. Section 745A(a) Providing Regulatory Submissions in Electronic Format. [2]
- OMB, 2012, M-12-18. Managing Government Records Directive.[3]
- FDA.gov, 2022, *eCTD File Format Specifications.*
- Guidance for Industry: *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. [4]
- FDA eCTD Waiver Committee web page[5]
- FDA, 2021, Center for Drug Evaluation and Research, MAPP 7610.7, CDER Data Standards Program.
- National Archives and Records Administration (NARA), Appendix A Tables of File Formats[6]

DEFINITIONS

Archivable: The ability of a document or file to be preserved for long-term use. For electronic documents or files, the ability to be archived is determined by the format. CDER only uses formats that are public, openly documented, and nonproprietary for CDER's electronic records.

CDER Applications: Collections of electronic documents filed by sponsors or applicants to CDER's review organizations for the review and approval of the use of human drugs and biologics. These documents are referred to as applications, namely New Drug Applications (NDAs), Biologics Licensed Applications (BLAs), Abbreviated New Drug

[2] https://www.fda.gov/files/drugs/published/Providing-Regulatory-Submissions-in-Electronic-Format-%E2%80%94-Submissions-Under-Section-745A%28a%29-of-the-Federal-Food--Drug--and-Cosmetic-Act.pdf
[3] https://www.archives.gov/files/records-mgmt/m-12-18.pdf
[4] https://www.fda.gov/media/135373/download
[5] *https://fda.sharepoint.com/sites/CDER-OMP-Collab/eCTD/SitePages/Home.aspx*
[6] https://www.archives.gov/records-mgmt/policy/transfer-guidance-tables.html

Applications, (ANDAs), Investigational New Drug Applications (INDs), and Drug Master Files (DMFs).

Electronic Common Technical Document (eCTD): The standard format for electronically submitting applications, amendments, supplements, and reports to CDER

eCTD File Format Specifications: This is a reference document which contains the recommended File Formats for documents within the eCTD submission.

Electronic Submission Coordinator: OBI staff member assigned to monitor and coordinate all efforts and agreements made between the division and sponsor or applicant, regarding the requesting and accepting of electronic materials for CDER applications. The Coordinator works for the Division of Data Management Services & Solutions (DDMSS) and reports to the Director, Office of Business Informatics (OBI).

Records: All recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor. Records are evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government, because of the informational value of data in them.

Records in electronic format: Records, as defined above, containing any combination of text, graphics, data, or other data represented in digital form submitted for regulatory purposes in an archivable format.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
11/17/99	Initial	n/a.
8/28/13	1	OBI (not review organization) is responsible for ensuring agreements between reviewers and sponsors/applicants for electronic material is consistent with CDER policy. Consultation lead time changed from 20 to 30 days. Response time from OBI to review organization changed from 10 to 15 days.

		MAPP applies to all CDER applications, not just NDAs. Added: • eCTD Specifications Guidance • Portable Document Format (PDF) Specifications Standardized Study Data Guidance • Structured Product Labeling Guidance Registration and Drug Listing Guidance
3/22/23	2	• Updated to reference eCTD 745A(a) guidance and associated specifications including File Format Specifications. • Changed MAPP title, for clarity. • Reorganized the RESPONSIBILITIES section. • Updated the PROCEDURES section. • Introduced the esub@fda.hhs.gov email box.
7/1/24	n/a	Corrected a typo.