## USER GUIDE

## ACCEPTABLE FILE TYPES FOR CVM ESUBMITTER

## I.     PURPOSE

The technical specifications outlined in this document are intended to facilitate electronic submissions to CVM, via eSubmitter. As part of FDA, CVM intends to be consistent where applicable with existing paradigms, file formats, and data standards developed by other FDA Centers. FDA and industry have both benefited from the use of technical standards in the past. Such benefits have included searchability, reliability, usefulness, accuracy, and assurance that the files within an eSubmission can remain accessible and legible into the future per FDA's records retention schedule. Standards have also facilitated the development of commercially available tools and services that support eSubmission creation and review.

Regulations in 21 CFR Part 11 require that the Agency be able to generate from any document provided in electronic format an accurate and complete paper copy that is both legible ("human readable") and suitable for inspection, review, and copying. Therefore, documents submitted in electronic format should:

- Enable the user to easily view a clear and legible copy of the information

- Enable the user to print each document page by page, as it would have been provided in paper, maintaining fonts, special orientations, table formats, and page numbers

- Include a well-structured table of contents and allow the user to navigate easily through the submission

- Allow the user to copy text and images electronically into common word processing documents

## II.     FILE NAMING CONVENTIONS

A submission may contain hundreds of individual files; therefore, clear and consistent naming of files) is helpful for both industry and the FDA reviewers. The use of certain characters can cause problems in processing submissions and cross-referencing files. We support upper and lowercase alphanumeric characters, underscores, dash/hyphen,

and spaces. Characters to avoid include spaces and special characters such as /, \, @, %, ; , non-English letters, and other non-alphanumeric symbols.

Descriptive and unique filenames across the entire eSubmission aid in locating information and communicating with the submitter about specific files. Unique file names also help prevent the overwriting of files upon upload into review systems that may use different folder or directory structures.

Concise, abbreviated filenames of less than 100 characters followed by the file extension indicating file format is usually sufficient to describe and distinguish files.

## III. FILE SIZE

CVM eSubmitter has been validated to create submissions of up to 10GBs, in which each individual file within the submission does not exceed 100MB. Such a submission, for example, may take several hours for CVM eSubmitter to package and will result in multiple zip files, each usually under 1GB.  Performance is improved when all files to be attached reside locally on the PC running the eSubmitter software. If your submission is great than 10 GBs, please contact the CVM eSubmitter helpdesk. (CVMeSubmitter@fda.hhs.gov)

## IV. ACCEPTABLE FILE FORMAT TYPES

CVM is able to receive, process, review, and archive many commonly used file types, also referred to as file formats. This helps ensure that an appropriate file format is available for each of the different kinds of content an applicant may want to include in its eSubmission. Table 1 lists formats most appropriate for each kind of content.

**Table 1: Supported File Format List with Descriptions**

| File Format Description | Filename Extension(s) | Appropriate Uses |
|---|---|---|
| Comma Separated Values | CSV | Supporting data and data tables with delimiters, table of contents and small data sets. Used in rare cases when appropriate. If you plan to use this format, contact CVM prior to submitting. |
| JPEG Image | JPG, JPEG | Photographs, graphs, charts, exemplar images of labeling and promotional materials |
| MPEG Audio Stream, Layer III | MP3 | Audio for promotional material, or to support study information |

| File Format Description | Filename Extension(s) | Appropriate Uses |
|---|---|---|
| MPEG-4 Video | MP4 | Video for promotional material or to support study information |
| Portable Document Format | PDF | Documents, formal reports containing narrative text and images |
| Standard Text File | TXT | Supporting data and data tables, extracted text from documents, programming code and procedures. Used in rare cases when appropriate. If you plan to use this format, contact CVM prior to submitting. |
| Extensible Markup Language | XML | Data, programming code, define files for data submitted in SEND or SDTM |
| SAS Transport | XPT, XPORT (not CPORT) | Data and data tables, including SEND or SDTM datasets. |

## V. SPECIAL CONSIDERATIONS FOR PORTABLE DOCUMENT FORMAT (PDF)

PDF is an open publishing format created by Adobe Systems Incorporated and later adopted by the International Organization for Standardization as ISO 32000-1:2008. PDF is utilized by FDA in its eSubmissions standards for document content of a narrative nature. Software from a variety of sources can be used to create files in PDF format 8.

CVM can receive and process PDF versions 1.4-1.7, PDF/A-1, PDF/A-2 and beyond. The readability of PDF files by Adobe Acrobat X, or above is one indicator that these files can be read by CVM. PDF files should not require additional software or plug-ins to be read, navigated, text-searched, text-selected, or printed.

PDF files should never be encrypted. CVM does not support the transmission of encrypted PDF files.

PDF files should not contain: JavaScript; dynamic content that can include audio, video or special effects and animations; attachments; 3D content; or annotations.

Hypertext links between individual PDF document files are not currently supported and any absolute links that reference across files will not work.

In general, for documents with a table of contents, provide bookmarks and hypertext links for each item listed in the table of contents including all tables, figures, publications, other references, and appendices. These bookmarks and hypertext links are essential for the efficient navigation through documents.

**A. Fast Web View Optimization**

"Optimize the PDF for fast web view" is an option available when generating PDF documents. It provides for a more responsive display of the first page of each PDF when viewing from tools that use a web interface. This can facilitate a reviewer's interaction with the documents as he or she navigates across content, which is beneficial to the review process.

**B. Initial View Settings**

"Bookmarks Panel and Page" is an option under PDF document settings that sets the initial document view upon opening to display an entire page and a left-side panel showing bookmarks to document content, allowing more expeditious navigation. If there are no bookmarks, set the Navigation Tab to "Page Only." Page Layout and Magnification can remain as "Default."

**C. Page Numbering**

In general, including the page number on each page of a PDF document, with the initial page of the PDF document numbered as page 1, facilitates navigation of and correspondence about electronic documents. Pagination should occur on an individual attached file basis.

**D. PDF Portfolio Files**

Certain applications will, by default, create PDF Portfolio files when converting files to a PDF format. **eSubmitter does not support the use of PDF Portfolio files** due to non-supported files may be embedded into Portfolio files.