ELECTRONIC SUBMISSION FILE FORMATS AND SPECIFICATIONS

Orientation and Best Practices
For
Data Formats and Submissions
To
The Center For Tobacco Products

For questions regarding this document,
contact CTP at CTPeSub@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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INTRODUCTION

This document provides orientation and technical file formats and data specifications helpful to submitting electronic files to the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). Recognizing that data can be submitted either via paper or electronic modes, this document speaks directly to the mechanisms and data formats associated with electronic submissions to CTP. The following specific goals of this document:

1. Provide specific answers and recommendations on data types, file sizes and formatting issues.
2. Briefly explain the tools available for submission to CTP.
3. Help the reader avoid mistakes before they happen.
4. Provide answers to questions that have arisen when submitting electronic data to CTP.
5. Provide information to a broader audience involved in the creation of electronic submissions that support electronic submissions to CTP.

AUDIENCE

The target audience for this document is one who has advanced computer and information technology skills. Proficiency with data standards, ecommerce, electronic document formats, and understanding the strengths and limitation of operating systems and Web protocols are needed to understand the information presented in this document.

This specifications document provides information about file types and electronic submissions standards that CTP may reference in various industry guidance and user guides. It is intended as a reference and provides strategies and considerations on creating and submitting electronic files to CTP. CTP guidance may cite content within this document, especially where such guidances discuss the submittal of data[1] and electronic submissions so that they can be received, processed, reviewed, and archived by the Center.

For the purposes of this document, the use of the word "supports" means the receiving Center has processes and technology infrastructure to enable it to receive, process, review, and archive files of the specified formats. Specifications within this document do not supersede guidance should there be a conflict.

These specifications, as with FDA guidance documents, do not establish legally enforceable requirements or responsibilities. Any use of the word *should* in these specifications means that something is suggested or recommended, but not required.

GENERAL CONSIDERATIONS

The technical specifications contained within this document are intended to assist applicants in electronically submitting files to CTP. As part of the FDA, CTP intends to be consistent (where applicable) with existing paradigms, file formats, and data standards developed by other Centers pertaining to electronic submissions and data standards. FDA and industry have both benefited in the past from the use of technical standards. Such benefits have included searchability, reliability, usefulness, accuracy, and assurance that files can be accessed and still read into the future. Standards have also facilitated the development of supporting solutions by the commercial market for eSubmission creation and review.

[1] For the purposes of this document, "data" are defined to be static, real values and information contained within a file that do not change or derive upon opening and viewing. For example, calculated values displayed in a spreadsheet using an embedded formula would not be considered data but would instead be considered as a formula supporting a defined process or method. Data resulting from such formulas should be submitted separately as values if those data are in support of a submission to CTP.

LIST of FILES
Because electronic submissions can be complex and, in some cases very large, providing a list of files ensures that all files that were intended to be sent were received. Such a list may be in the form of a table of contents (TOC) within the body of a submission document or a separate index of files outside of the TOC.

eSUBMITTER
eSubmitter helps a user create an electronic submission. It is provided by FDA as a free, stand-alone software. It is downloaded and run on a submitter's desktop. eSubmitter guides the user through the process of entering information and attaching files. It provides screens and functions for capturing data about the applicant, application, and products, and also allows the attachment of files. The eSubmitter software, and all associated data and files, reside locally on the user's computer, allowing users to build their submission packages offline or use information from a prior submission to start from when creating a new submission. The FDA does not have the ability to access or view the submission information on a user's computer.

eSubmitter then packages all data and attachments into a zip file which the user can then submit to CTP via CTP Portal, ESG/WebTrader, or burn onto physical media (e.g., DVD) and mailed. It is helpful for the contact information within the eSubmitter submission to match the contact information within the CTP Portal account.

More information on eSubmitter and how to download it is located on the FDA Website at http://www.fda.gov/ForIndustry/FDAeSubmitter/.

The following table 01 provides a list data elements used in eSubmitter that associated with a submission package output by eSubmitter.

Table 01, Specifications of key data elements within eSubmitter

Data Element	Type	Data Element	Type
Establishment Name	VARCHAR2(50)	Zip Code	INTEGER(5)
FDA Establishment Identified (FEI)	VARCHAR2(10)	Zip Code Ext	INTEGER(4)
DUNS Number	VARCHAR2(9)	Province/Territory	VARCHAR2(100)
Product Name	VARCHAR2(120)	Postal Code	VARCHAR2(10)
Submission Tracking Number (STN)	VARCHAR2(9) *(XX123456789)*	Country Code	VARCHAR2(3) *NIST GENC 3*
First Name	VARCHAR2(100)	Phone Area Code	INTEGER(3)
Middle Name	VARCHAR2(100)	Phone Exchange	INTEGER(3)
Last Name	VARCHAR2(100)	Phone LineNumber	INTEGER(4)
Title Name	VARCHAR2(4)	Phone Ext	INTEGER(5)
Address Line 1	VARCHAR2(100)	Phone International	VARCHAR2(20)
Address Line 2	VARCHAR2(100)	File Name	VARCHAR2(255)
City	VARCHAR2(100)	File Title	VARCHAR2(400)
State Code	VARCHAR2(5)	Dates (of any kind)	DATE

SECURITY
The Federal Information Security Modernization Act of 2014 (44 U.S.C. § 3551–58) requires FDA to ensure the integrity, confidentiality, and availability of its electronic records. Electronic content received by the FDA must be free of computer viruses and spyware which could introduce vulnerabilities, and compromise record integrity as well as FDA's ability to process the records.

Security settings, encryption, and password protection can render files (*e.g.*, PDF) inaccessible or unmanageable for review, storage, and retrieval by the Agency. Such settings can also render content difficult to search, select then copy text, and print. FDA forms in PDF format available from the FDA website may contain security settings that prevent changing the essential elements of the form, however, the security on these forms do not impede their use, search, and storage. These forms should be submitted with their existing security settings.

For information technology (IT) security reasons and due to Federal records and redaction requirements, CTP cannot generally receive and process files that are of an active nature such as files that contain macros (active files), executables (.exe), command files (.com), visual basic scripts (.vbs), DOS Batch files (.bat). However, accommodations can be made in advance of receipt when

such files are required for review such as programs and apps.

FILE FORMAT TYPES

CTP is able to receive, process, review, and archive many commonly used file types, also referred to as file formats. This helps ensure an appropriate file format is available for each of the different kinds of content an applicant may want to submit. Table 02 (below) lists formats most appropriate for each kind of content.

Table 02, Supported File Format List with Descriptions

File Format Description	Filename Extension(s)	Appropriate Usages
Ascii Text	TXT	supporting data and data tables, extracted text from documents, programming code and procedures
Bitmap Graphics	BMP	Images
Cascading Style Sheets	CSS	documents, consumer web page content
Chemical Markup Language	CML	Open standard in XML format for molecular and chemical data
Comma Separated Values	CSV	supporting data and data tables with delimiters, table of contents
Data Type Definition	DTD	definition of data submitted within XML datasets. for study data as well as electronic submission standards for content, e.g., eCTD backbone.
Excel	XLS, XLSX	Alternative container for data and formulas
Extensible Markup Language	XML*	study data, tables of content, electronic submission standards for content, e.g., eCTD backbone.
Extensible Stylesheet Language	XSL	layout, formatting of content for that has been provided in XML format.
GIS Data format	KML*	Geographic location data in XML format
Graphic Interchange Format (CompuServe)	GIF	photographs, graphs, charts, exemplar images of labeling and promotional materials
HyperText Markup Language	HTM, HTML	documents, consumer web page content
JPEG Image	JPG	photographs, graphs, charts, exemplar images of labeling and promotional materials
Molecular Design Limited MOL file	MOL	A MOL file for information about a molecule, e.g., atoms, bonds, connectivity and coordinates
Moving Picture Experts Group	MPEG	Video, for promotional material, molecular rotation
MPEG Audio Stream, Layer III	MP3	Audio, for promotional material
MPEG-4 Video	MP4	Audio, for promotional material
Portable Document Format	PDF	Documents, formal reports containing narrative text and images
Portable Network Graphics	PNG	Images
QuickTime movie file	MOV	Video, for promotional material, molecular rotation
SAS Transport	XPT*, XPORT (not CPORT)	data and data tables and SAS program code (see more information below at Analysis Datasets section)
Scalable Vector Graphics	SVG	Images
Structured Data File	SDF	For the chemical data structure, wraps MDL
Windows Media File	WMV	Video

Windows Waveform Sound	WAV	Audio, for promotional material
XML Schema	XSD	layout, formatting of content for that has been provided in XML format.

ANALYSIS DATASETS

The Statistical Analysis System (SAS) transport file (.xpt) format is recommended for analysis datasets. SAS transport files may be created with the XPORT engine in SAS Version 6 and later, or by using PROC XCOPY in SAS Version 5 format. XPORT is an open format, while CPORT is a proprietary format. The following link provides additional information for preparing SAS.xpt files to meet FDA submission standards:
<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>

Comma separated values (CSV) file is an alternative to SAS transport files and is a text file where data are separated by a comma delimiter with carriage returns at the end of each row. If other delimiters are used to separate values, it will be necessary to identify the delimiter in the body of the submission or in the index of files so that the data can be properly parsed and utilized. It is common for the first row in a CSV file to contain column headers naming the data domain of each data column.

FILE SIZE

File sizes recommended throughout FDA guidances and other documents can vary by file type. File size recommendations are based upon technical limitations inherent to the file type itself or FDA's experience with problems processing, opening, reviewing, or redacting files. For example, PDF file sizes greater than 500 MB have presented difficulties which resulted in the need for resubmittal of a portion of the submission. Individual datasets and files containing photographic images can exceed 500 MB but problems can occur beyond 2 GB.

FONTS

PDF viewing software automatically substitutes fonts to display textual content if the specified font is unavailable on the user's computer. Font substitution can affect a document's appearance and formatting, and in some cases, can affect the information conveyed by a document. For an FDA reviewer, this means they may see content that is not exactly as an applicant intended or as it was last viewed. Font substitution can occur even when the fonts are available. For example, Helvetica or Times may be substituted even if these font sets are available on the reviewer's computer.

Embedding non-standard fonts will ensure that content is displayed properly and correctly as intended by the applicant. Font availability to the reviewer is ensured if all non-standard fonts are fully embedded. When fonts are embedded, all characters defining the font set should be included—not just a subset of the fonts being used in the document.

Even with the embedding of non-standard fonts, problems can remain. For example, when text is selected and copied to the clipboard for eventual pasting into another document, such as an FDA review, the resulting text can appear different. Table 03 lists standard fonts to consider as they are available on most computers, including FDA computers.

Font sizes of at least 9 point ensures legibility and Times New Roman and Calibri 12-point font are common for narrative content. The Sans Serif font family provides optimal visibility on screen and print, requires less ink to print, and facilitates more accurate OCR if pages require scanning. When choosing a font point size for tabular information, considerations of font size may be offset by the advantages of presenting the table across as few pages as possible to facilitate data comparisons while still achieving a font size that remains legible. Font sizes of 9 to 10 are common for tables and data sets for when data must be presented within the narrative body of a submission in PDF format. Small point sizes are commonly used for footnotes. Font size does not pertain to data file formats such as csv, txt, xml, and SAS datasets.

Resizing of scanned images and scanned text can shrink and deform the content thus reducing legibility and printability. Black and high contrast colors against an opposing background facilitates legibility. Light colors display poorly against light backgrounds and print poorly on grayscale printers.

Table 03: List of Standard Fonts

Font type	Font name
Serif	Times New Roman
	Times New Roman Italic
	Times New Roman Bold
	Times New Roman Bold Italic
	Garamond
	Garamond Italic
	Garamond Bold
	Garamond Bold Italic
Sans Serif	Arial
	Arial Italic
	Arial Bold
	Arial Bold Italic
	Calibri
	Calibri Italic
	Calibri Bold
	Calibri Bold Italic
Non-Proportional	Courier New
	Courier New Italic
	Courier New Bold
	Courier New Bold Italic
Other	Symbol
	Windings (Zapf Dingbats)
	Webdings

PAGE ORIENTATION

Page orientation can vary from page to page, as needed for the most appropriate viewing and printing within a submission. Appropriate page orientation eliminates the need for reviewers to rotate pages or monitors to read content. For example, setting page orientation of a wide table to landscape prior to saving into a document format such as PDF or printing can ensure all columns fit onto one wide page and that the page is displayed in a top to bottom orientation that does not require rotation to read on a monitor.

PAGE SIZE AND MARGINS

Formatting pages to fit on a sheet of paper that is 8.5 inches by 11 inches (letter size) or 8.5 inches by 14 inches (legal size) facilitates viewing on standard monitors and printing. A margin of at least 3/4 of an inch on the left side of page avoids obscuring information should pages ever need to be printed and bound. Setting the margin for at least 3/8 of an inch is sufficient for the right side. For pages in landscape orientation, a margin of 3/4 of an inch at the top allows more information to be displayed legibly on the page. Header and footer information should not invade the specified margins (i.e., header and footer information should not appear within 3/8 of an inch of the edge of an 8.5 by 11 inch page), so the text will not be lost upon printing or being bound. These margins allow printing on A4 as well. Oversized documents (e.g., Computer Aided Design CAD drawings, facility diagrams) and promotional materials submitted in an image or document format should be created according to their actual page size.

SCANNING OF PAPER DOCUMENTS

Electronic document files produced by the scanning of paper documents initially result in photographic images of text and data, are not recognizable as functional text on a computer for the purposes of searching and text selection, and are susceptible to issues that impact photography. Additional processing is necessary for text to be recognized from the images through a process called optical character recognition (OCR). Scanned documents with OCR may produce documents of poor quality such as missing and incorrect characters underlying the images of words. The sensitivity and specificity of OCR software varies and some OCR software provides for the ability to adjust these parameters and to validate the resulting text. Also, resulting file sizes of scanned documents are significantly larger than equivalent PDF documents, for example, documents generated directly from their source files which have been saved to a PDF format or printed to PDF printer driver. PDF is a common and useful format for documents originating from paper that have been scanned and then OCRed, since they can be combined with other PDF documents within a larger submission and then can be navigated and searched as one.

FDA recommends minimum image resolutions for scanned documents, depending upon the nature of the content[2], (see Table 04) and these are also suitable for tobacco product submissions. Documents scanned at a resolution of 300 dots per inch (dpi) ensure that the pages of the document are legible both on the computer screen and when printed and, at the same time, minimizes the file size. The use of grayscale and color significantly increases the file size and should be used only when these features improve the reviewability of the material. After scanning, avoid resampling to a lower resolution. A captured image should not be subjected to non-uniform scaling (i.e., sizing).

Table 04: Document and Image Scanning Resolutions

Document type	**Minimum Resolution** dots per inch (dpi) to ensure legibility
Handwritten notes	300 dpi (black ink)
Plotter output graphics	300 dpi
Photographs - black and white	600 dpi (8 bit gray scale)
Photographs – color	600 dpi (24 bit RGB)
Gels and karyotypes	600 dpi (8 bit grayscale depth)
High pressure liquid chromatography	300 dpi

IMAGE COLOR MATCHING

Because color varies from monitor to monitor, it is difficult to ensure that the reviewer will see exactly the same color as in the original image. However, for printing, there is more control over the color by using the CMYK (Cyan, Magenta, Yellow, Black) color model as opposed to the RGB model. Pantone Matching using the color profile provided by CMYK ensures color consistency for printing. The International Color Consortium (ICC)[3] color profile specification is used when PDF documents are printed.

FILE and FOLDER NAMING CONVENTION

A submission may contain hundreds of individual files and so clear and consistent naming of files and folders (directories) is helpful for both industry and FDA reviewers. The submission unit that contains the main table of contents is called the main submission unit since it is the starting point for navigation and review. This main submission unit may also contain the bulk of the narrative. Clearly naming this file as "Main-TOC.pdf" will help ensure that all parties know the file to begin with and navigate from.

The use of certain characters can cause problems in processing submissions and cross-referencing files. Characters to avoid include spaces and special characters such as / \, @, %, non-English letters, and other non-alphanumeric symbols. The current FDA validation criteria and the ICH eCTD specification both provide additional guidance on special characters in file names.

Descriptive and unique files names and folders across the entire submission 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 which may use differing folder or directory structures.

Concise, abbreviated filenames of less than 50 characters followed by the file extension indicating file format is usually sufficient to describe and distinguish files apart. Also, a file path is the string of text that specifies the location of each file and includes folders, subfolders, and the full filename. However, this path is limited to 255 characters in the Windows environment and on the Internet. Both the Applicant and FDA will be operating under this constraint and the FDA will need 75 characters of this path length remaining to make use of for when it loads files into its own subfolders and systems. Therefore, file paths within eSubmissions can utilize up to 180 characters while still enabling FDA the additional characters it needs to process and install a submission into its systems.

DOCUMENT NAVIGATION

A table of contents (TOC), hypertext links and bookmarks assist in navigation throughout the body of a submission. CTP recommends including a hypertext linked TOC and bookmarks in documents greater than 5 pages. Hypertext links help the reader navigate to references, related sections,

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[2] Portable Document Format Specification, CDER/CBER, Sep. 2014, and, Guidance to Industry- Providing Regulatory Submissions in Electronic Format, General Considerations, CDER/CBER, Jan. 1999.

[3] **http://www.color.org/**

appendices, tables and figures that are not on the same page as the narrative text. Hypertext links in text can be designated by rectangles using thin lines or by blue text. A consistent method of designating links in a document avoids confusion. Hypertext links that open a file or document should be set to open the file or document in a new window. A relative path specifies the location of a file from the current directory downward, and does not include the specific drive letter and parent directories above the current location. Using relative paths when creating hypertext links minimizes the loss of hyperlink functionality when submissions are loaded onto network servers; both absolute links that reference specific drives and links to root directories do not work once the submission is loaded.

The document TOC (main-toc.pdf) helps the reviewer navigate to the information of interest within the document that is not provided in the submission table of contents. For documents with a table of contents, CTP recommends providing bookmarks and hypertext links for each item listed in the table of contents including all tables, figures, publications, other references, and appendices that are essential for navigation through documents. When creating links in tables of contents and throughout submission documents, the current Internet standard is to use invisible rectangles and blue text which avoids obscuring text in the table of contents for hypertext links. Other help for navigation includes a bookmark hierarchy identical to the table of contents; up to four levels deep in the hierarchy.

When creating bookmarks and hyperlinks, setting the magnification to "Inherit Zoom" is helpful as it ensures that all pages during the review open and display at the same magnification level of the primary document.

SPECIAL CONSIDERATIONS FOR PORTABLE DOCUMENT FORMAT (PDF)

Portable Document Format (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 the FDA in its electronic submissions standards for document content of a narrative nature. Software from a variety of sources can be used to create files in the PDF format.
Reference: ISO 32000-1:2008 - Document management – Portable document format – Part 1: PDF 1.7". ISO.org. 2008-07-01. <http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=51502>

PDF versions 1.4 through 1.7, PDF/A-1, PDF/A-2 and beyond can be received and processed by CTP. The readability of PDF files by Adobe Acrobat X, or above, is one indicator that these files can be read by CTP. PDF files should not require additional software or plug-ins to be read, navigated, and text searchable, selectable, or printed.

PDF files should not contain: JavaScript; dynamic content which can include audio, video or special effects and animations; attachments or 3D content; or annotations.
Hypertext links in documents should be tested that they remain active after conversion to PDF/A.
Promotional materials (*e.g.*, labeling and advertising) submitted in PDF format may need special consideration to ensure accurate and unaltered presentation.

Fast Web View Optimization-
"Optimize the PDF for fast web view" is an option available when generating a PDF document. 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 document as he or she navigates across content which is beneficial to the review process.

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

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 one, facilitates navigation of and correspondence about electronic documents. There is an exception when a document is split because of its size (e.g., > 500 MB) and the second or subsequent file is numbered consecutively to that of the first or preceding file.

SPECIAL CONSIDERATIONS FOR PROMOTIONAL MATERIAL

Promotional materials (*e.g.*, labeling and advertising) submitted in PDF format may need special consideration to ensure accurate representation of the actual image. Since color varies from monitor to monitor, it is difficult to ensure that the reviewer will see exactly the same color as in the original image. CTP recommends providing images at the highest resolution and depth practical. For photographs, CTP recommends providing the image with at a resolution of at least 600 dpi to ensure it can be accurately read. When source documents are available only in paper and scanned into electronic forma, the resolution is important to ensure that pages are legible both on the computer monitor and when printed; at least 600 dpi is usually sufficient. Promotional material submitted according to its actual size, when practical, is most effective in ensuring it is presented and reviewed as it will actually exist on the market. When an image size is altered, it is important that the original dimensions be stated in order to understand how it will appear on the market. Images of three-dimensional promotional pieces constitute multiple sides and components. Providing all sides and components of such pieces will help ensure it can be reviewed.

STANDARDS FOR USE IN eSUBMISSIONS TO CTP

The following data and electronic submission standards may be helpful in facilitating a quality and facilitative electronic submission The data standards listed in Table 05 represent key standards that CTP recommends for use in eSubmissions to the Center.

Table 05: Structure and Content Standards

Standard	Description	Reference
MedDRA	Medical Dictionary for Regulatory Activities. A standard developed through the International Conference on Harmonization (ICH) for medical terminology for use in regulatory communications and evaluation of data pertaining to human medical products	http://www.meddra.org/
UNII	Unique Identifiers for products and substances- • Unique Ingredient Identifiers (UNIIs), for substances in drugs, biologics, foods, and devices.	https://www.fda.gov/ScienceResearch/HealthInformatics/ucm474551.htm
WHODD	The WHO Drug Dictionary is an international classification of medicines created by the WHO Programm for International Drug Monitoring. organizations and drug regulatory authorities for identifying drug names in spontaneous ADR reporting (and pharmacovigilance) and in clinical trials.	https://www.who-umc.org/
ISO8601	International standard covering the exchange of date- and time-related data. It was issued by the International Organization for Standardization (ISO) and provides an unambiguous and well-defined method of representing dates and times particularly when data are transferred between countries with different conventions for writing numeric dates and times.	https://www.iso.org/standard/40874.html
ISO11238	Standard for defining and distinguishing substances in a product. Provides: a hierarchical model for products, consistent with HL7's Common Product model; and a model for substance categorization.	https://www.iso.org/standard/55031.html
IUPAC	International Union of Pure and Applied Chemistry (IUPAC): Develops recommendations to establish unambiguous, uniform, and consistent nomenclature and terminology for chemical disciplines, including definitions of terms relating to a group of properties; nomenclature of chemical compounds and their classes; terminology, symbols, and units; classifications and uses of terms; and conventions and standards of practice for presenting data.	https://iupac.org/what-we-do/nomenclature/
SNOMED	The Systematized Nomenclature of Medicine (SNOMED) is a systematic, computer-processable collection of medical terms, in human and veterinary medicine, to provide codes, terms, synonyms and definitions which cover anatomy, diseases, findings, procedures, microorganisms, substances, etc.	http://www.snomed.org/

Standard	Description	Reference
ICD	The International Classification of Diseases (ICD) is the international "standard diagnostic tool for epidemiology, health management and clinical purposes".	http://www.who.int/classifications/icd/en/
LOINC	Logical Observation Identifiers Names and Codes (LOINC) is a database and universal standard for identifying medical laboratory observations.	https://loinc.org/
eCTD	Electronic Common Technical Document. An international data standard developed by the ICH for capturing the content and organization of a submission and subscribing to the Common Technical Document (CTD) structure for regulatory applications for pharmaceutical product.	http://estri.ich.org/eCTD/ http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm
RPS	Regulated Product Submission. A later iteration of eCTD being developed under Health Level Seven International (HL7) and which will include message exchange between industry and regulatory agencies.	http://www.hl7.org http://wiki.hl7.org/index.php?title=Regulated_Product_Submissions http://www.fda.gov/ForIndustry/DataStandards/RegulatedProductSubmission/default.htm
SDTM	The Study Data Tabulation Model is a CDISC standard that provides a standard structure for human clinical trial (study) data tabulations and for nonclinical study data tabulations.	https://web.archive.org/web/20080612045554/http://www.cdisc.org/models/sdtm/v1.1/index.html
SEND	The Standard for Exchange of Nonclinical Data (SEND) is an implementation of the CDISC Standard Data Tabulation Model (SDTM) for nonclinical studies, which provides a way to present nonclinical data in a consistent format.	https://www.cdisc.org/standards/foundational/send
ADaM	Analysis Data Model (ADaM) is a CDISC standard that provides traceability between analysis results, analysis data, and data represented in the Study Data Tabulation Model (SDTM).	https://www.cdisc.org/standards/foundational/adam

TRANSMISSION MODES

Electronic submissions can be sent to CTP via the following modes:

- CTP Portal, which requires eSubmitter generated zip file. Refer to this URL for more details: https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm
- ESG/Web Trader, requires eSubmitter generated zip file. Refer to this URL for more details: https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/manufacturing/default.htm (submit online)
- Physical Media- CD-ROM, DVD, Hard Drives. Refer to this URL for more details: https://www.fda.gov/TobaccoProducts/AboutCTP/ContactUs/default.htm

TESTING OF CONTENT AND FORMAT PRIOR TO SUBMITTAL TO FDA

The testing of a submission by an applicant, before submittal to the FDA, can help detect issues and provide an applicant the opportunity to resolve problems. Such tests can include viewing, navigating, searching within text, selecting text, printing, and clicking on hyperlinks and bookmarks. While many document types may allow you to embed files within files, this can create problems for virus scanning or even submission through the FDA ESG and CTP Portal.

FDA encourages early consultation by persons intending to submit electronically, especially those making such an electronic submission for the first time.