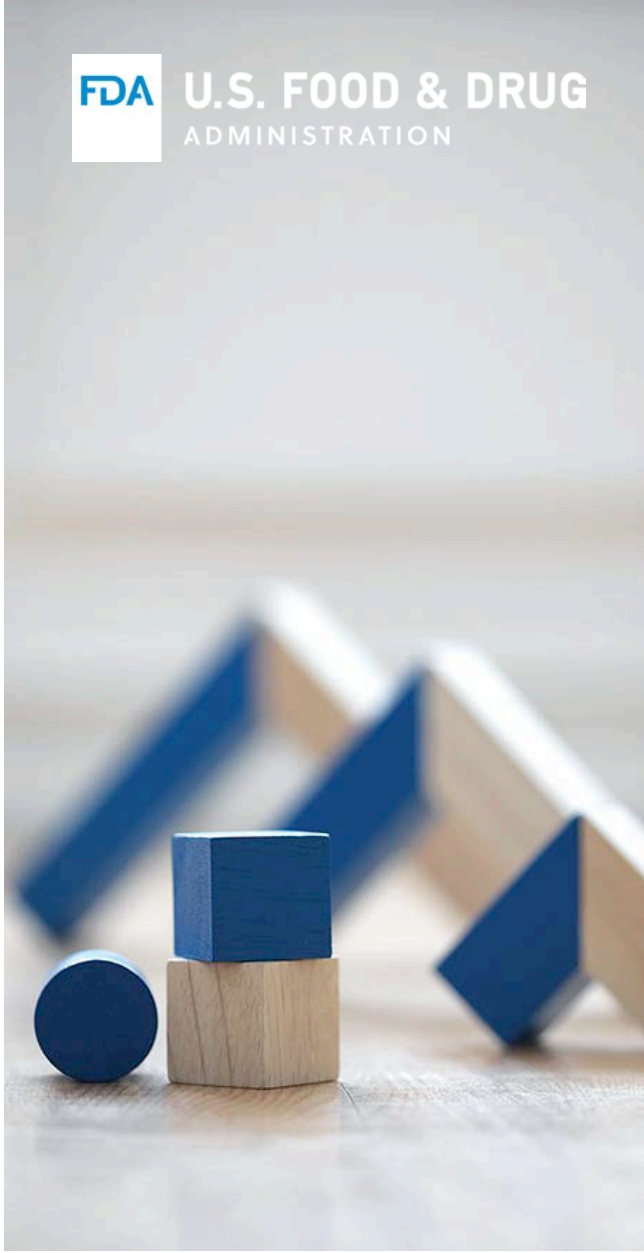
AN OVERVIEW OF THE ELECTRONIC SUBMISSIONS (ESUB) PROCESS FOR INDUSTRY

Center for Tobacco Products (CTP), Office of Science,
Division of Regulatory Science Informatics

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.



February 1, 2018

CENTER FOR TOBACCO PRODUCTS

PURPOSE

- Familiarize industry representatives with the eSub process.
- Summarize current standards and guidance.
- Provide resources.

INTENDED AUDIENCE

- Intended for tobacco industry representatives.
- This is a non-technical overview.
- However, the eSub Process requires technical expertise.

ESUBMISSIONS PROCESS

A high level view…

1. Compile relevant documents and data.
2. Create a submission package using eSubmitter.
3. Send the submission package Table of Contents to your CTP point of contact.
4. Request a meeting with CTP (optional).
5. Submit the package through CTP Portal.

ESUBMITTER

- Free software from the FDA.
- It aids in the creation and packaging of your submission.

- For more information and to download:

http://www.fda.gov/ForIndustry/FDAeSubmitter

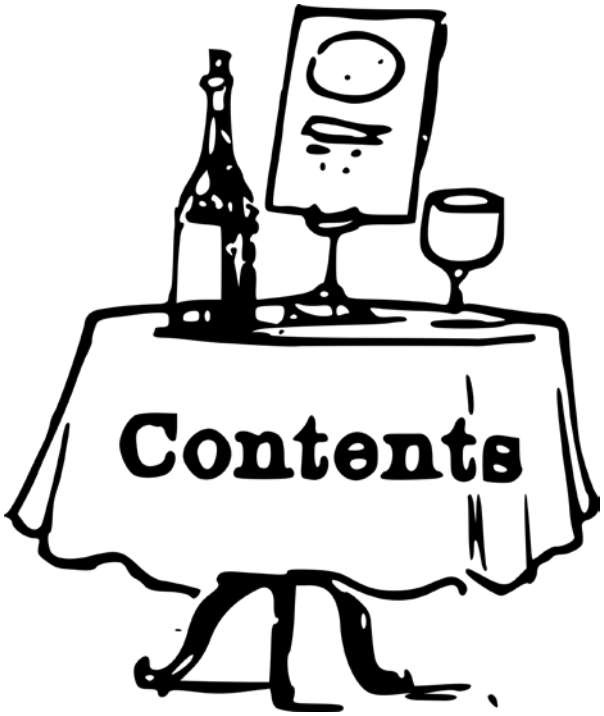
- Check out the Industry Quick Guide:

https://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM449759.pdf

Use FDA's eSubmitter software – it's FREE!

TABLE OF CONTENTS

- Always include a table of contents, also called a ‘Manifest,’ with your electronic submission.
- Send it to your CTP point of contact ahead of submission.



ACCEPTABLE FILE FORMATS

- An eSub package can include numerous files and file types.
- Some common file types are shown in the table to the right.
- For a full list of acceptable file types see the CTP eSub technical specifications document: https://fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM594504.pdf

File Format Description	Filename Extension(s)
Portable Document Format	PDF
Comma Separated Values	CSV
ASCII Text	TXT
JPEG Image	JPG
Graphic Interchange Format (CompuServe)	GIF
Microsoft Word, Microsoft Open XML	DOC, DOCX
SAS Transport	XPT
Extensible Markup Language	XML
GIS Data format	KML
Excel	XLS, XLSX
Moving Picture Experts Group	MPEG
QuickTime movie file	MOV
HyperText Markup Language	HTM, HTML
MPEG Audio Stream, Layer III	MP3

FILE AND DOCUMENT GUIDANCE

FILE SIZE

- Upper limit depends on file type
- Speak to the CTP Regulatory Health Project Manager assigned to your company about individual files larger than 10 gigabytes
- If there is no regulatory health project manager assigned to your submission or you have not yet submitted, please contact CTPeSub@fda.hhs.gov
- For eSubmitter technical support, e-mail esubmitter@fda.hhs.gov or call 1-877-CTP-1373.

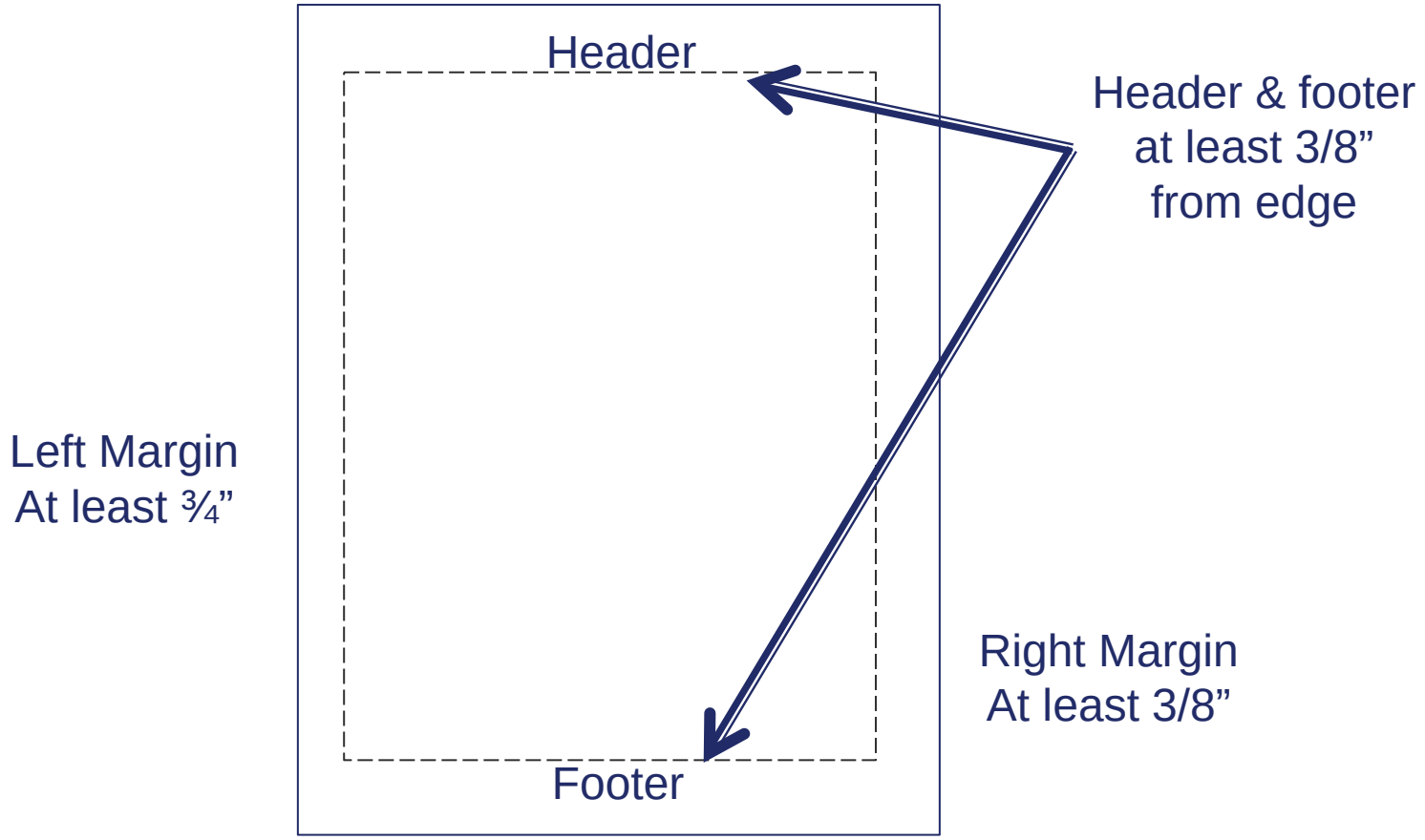
FONTS

- Use fonts that are standard on Windows and Mac computers, for example: Arial, Calibri, Helvetica, and Times New Roman
- Font sizes of at least 9 point ensures legibility for review
- 12-point font is the most common size for narrative content

Aa Bb Cc Dd Ee Ff Gg Hh Ii Jj Kk Ll Mm

NARRATIVE PAGE LAYOUT EXAMPLE*

8.5 x 11 inch page

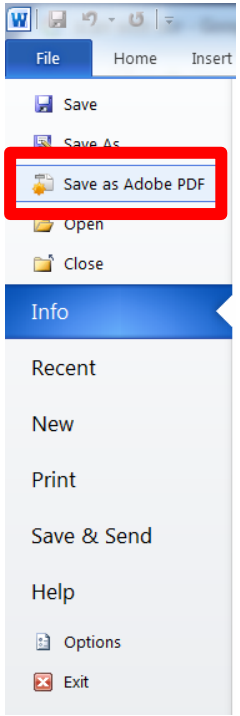


** Diagrams and images may require different page layouts*

SCANNING PAPER DOCUMENTS

- Use Optical Character Recognition (OCR) if possible.
- Generate PDFs from the source document
  - e.g. in Microsoft Word, click File, then Save as Adobe PDF
- For more information about OCR visit:

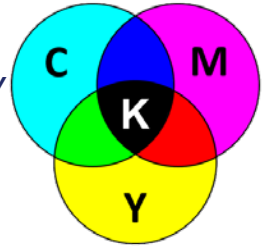
  https://en.wikipedia.org/wiki/Optical_character_recognition



DOCUMENT AND IMAGE RESOLUTION

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)
Chromatography Plot	300 dpi

**Use the CMYK (cyan, magenta, yellow, black) color model to ensure consistency across monitors and when printing.*



FILE & FOLDER NAMING RULES

FILE & FOLDER NAMING – RULE 1

- No special characters
- Examples of special characters to avoid:
  - **/ \ @ % < > ” ? | : ;**
  - Non-English characters such as **ä, é, î, ð, ñ, ü, æ**

FILE & FOLDER NAMING – RULE 2

- Limit individual file names to at most 50 characters (not including the file extension, e.g. .docx, .xlsx, .pdf, .xpt).

- The following example has 49 characters:

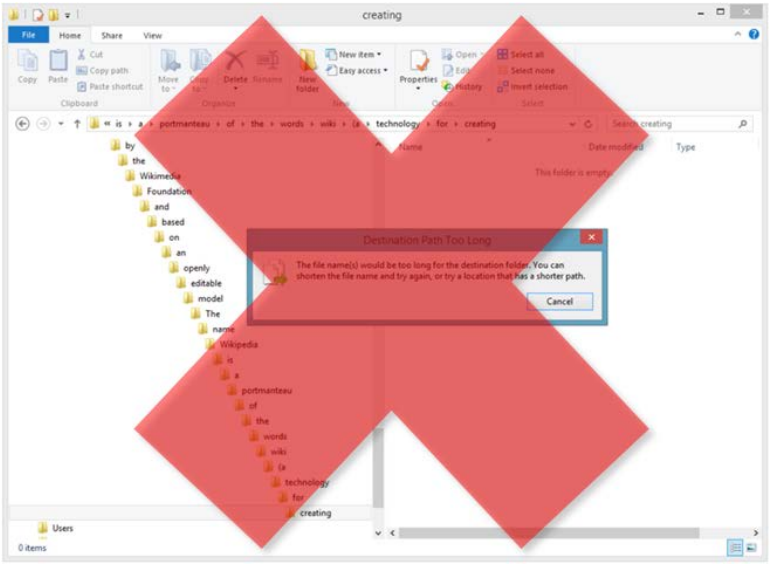
Submission_application_packet_number_v15_05-20-17.docx

FILE & FOLDER NAMING – RULE 3

- File paths should not exceed 180 characters.

  [Note: The Windows file path limit is 255 characters, but FDA will use up to 75 characters to load eSub documents into folders for Reviewers.]

- Be mindful of the number of folder levels in your submission.



DOCUMENT NAVIGATION

- Provide a hypertext linked table of contents and bookmarks in any PDF document longer than 5 pages.

- Hyperlinks should open in a new window.

CONSIDERATIONS FOR PDF DOCUMENTS

- Use fast web view optimization.
- Set bookmarks panel and page.
- Page number and file page should be the same.
- Set magnification to inherit zoom.
- Must not contain JavaScript or embedded audio, video, animation, 3D content, or annotations.

PROMOTIONAL MATERIALS

- Submit according to actual size when practical.
- Images of 3D promotional pieces must show all sides and components.

TESTING

- Test submissions are encouraged!
- Speak to your CTP point of contact to submit test documents prior to your full eSubmission.
- Testing can uncover issues prior to full submission – saving you time and speeding the review process.

SUBMITTING YOUR APPLICATION

- CTP developed CTP Portal to improve submission processing.
- Submit your application via CTP Portal, if possible.
- If you are unable to submit via CTP Portal, visit the Manufacturing web page for other options for submitting your application package: https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm

CONCLUSION

- eSubmission is a technical process – consult with your IT staff or a vendor.
- Following these guidelines will save you time and facilitate review of your application.
- Speak to your CTP point of contact early and often.
- Visit the Using eSubmitter to Prepare Tobacco Product Submissions web page for more details and helpful hints: https://www.fda.gov/forindustry/fdaesubmitter/ucm189469.htm

FDA RESOURCES

FDA eSubmitter: https://www.fda.gov/ForIndustry/FDAeSubmitter/

eSubmitter Quick Guide: https://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM449759.pdf

FDA eSubmitter User Manual:
https://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM449759.pdf

FDA Electronic Submissions Gateway (ESG):
https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

CTP Portal:
https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm

Data Standards: https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

Electronic Regulatory Submission and Review:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/default.htm

FOR MORE INFORMATION

Or to ask a question, contact:

For eSubmitter technical support,
email esubmitter@fda.hhs.gov
1-877-CTP-1373

For CTP - Guidance or the Tobacco Control Act questions
TobaccoIndustryQuestions@fda.hhs.gov

For the CTP Portal support,
email CTPeSub@fda.hhs.gov.