TOBACCO PRODUCT MASTER FILES (TPMFS)

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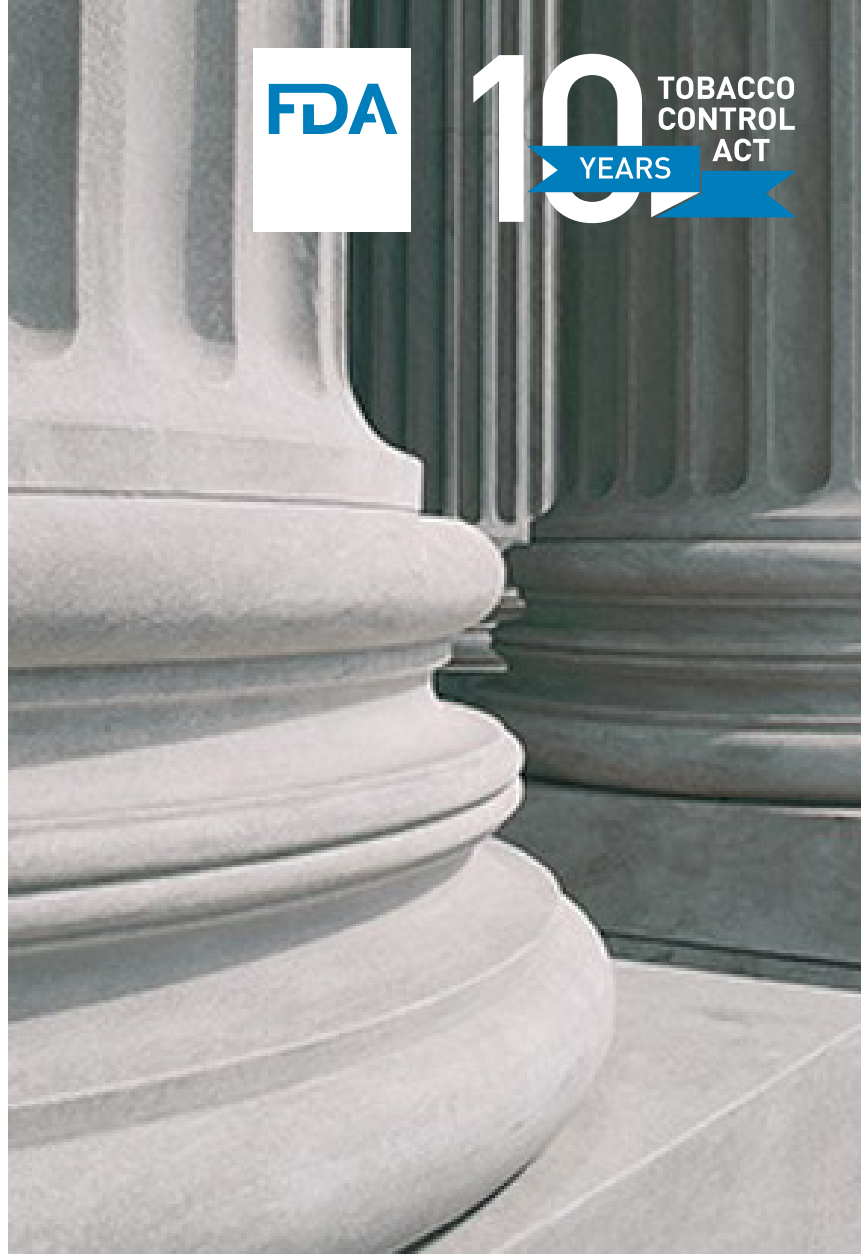

AGENDA

- Overview
- Key Terms
- How to Organize a TPMF
- How to Establish a TPMF
- How to Amend a TPMF
- How to Reference a TPMF
- How a TPMF is Reviewed
- Key Take Home Points

OVERVIEW

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- A TPMF is a file voluntarily submitted to CTP that contains trade secret and/or confidential commercial information about a tobacco product or component that the owner does not want to share with other persons.

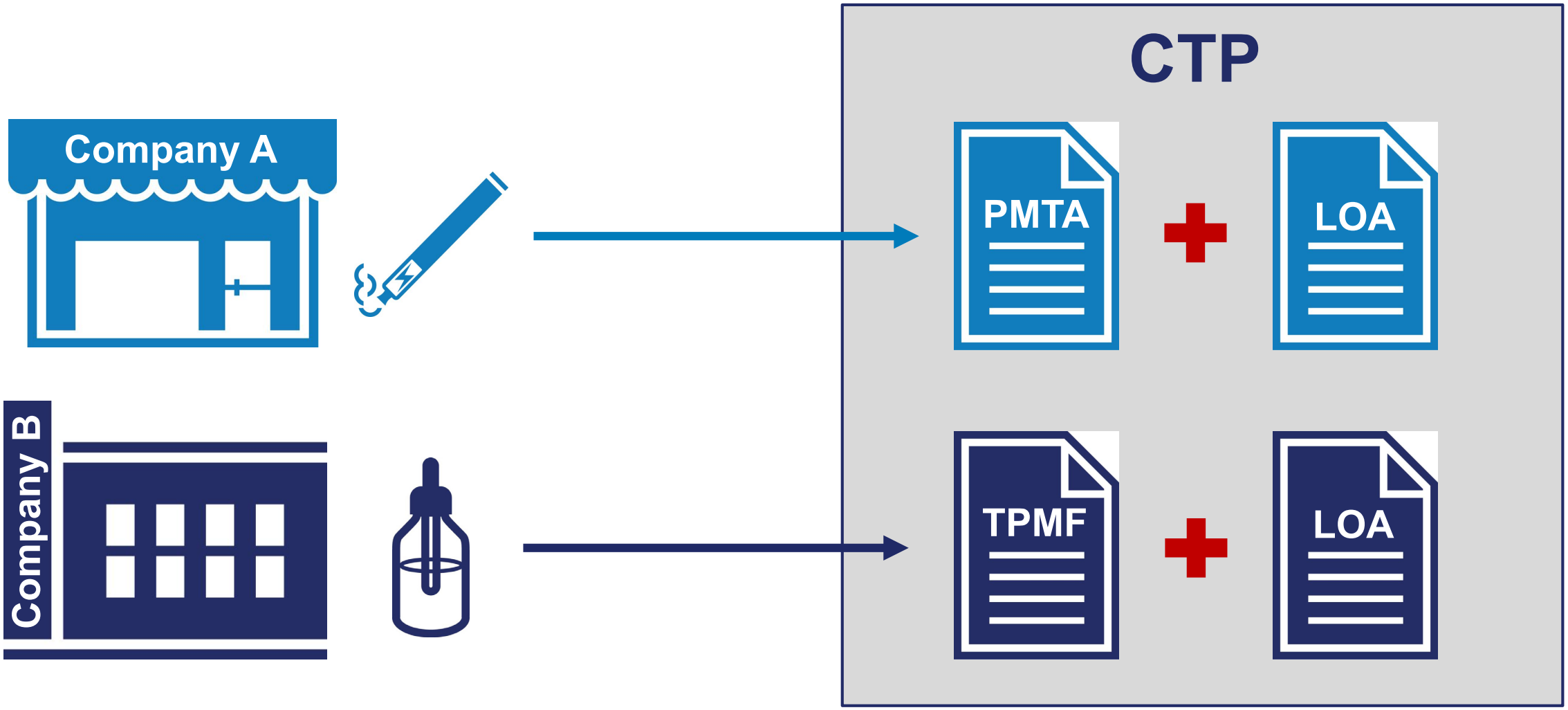
- TPMFs are a beneficial tool for manufacturers, component suppliers, ingredient suppliers, and researchers, and can assist the tobacco product submission process.

OVERVIEW

- A TPMF owner allows an authorized party the right to reference the TPMF in support of a tobacco product submission to CTP.

- CTP can then access and review the confidential information as part of their submission, but at no point in time does the authorized party see or have access to the confidential information.

OVERVIEW

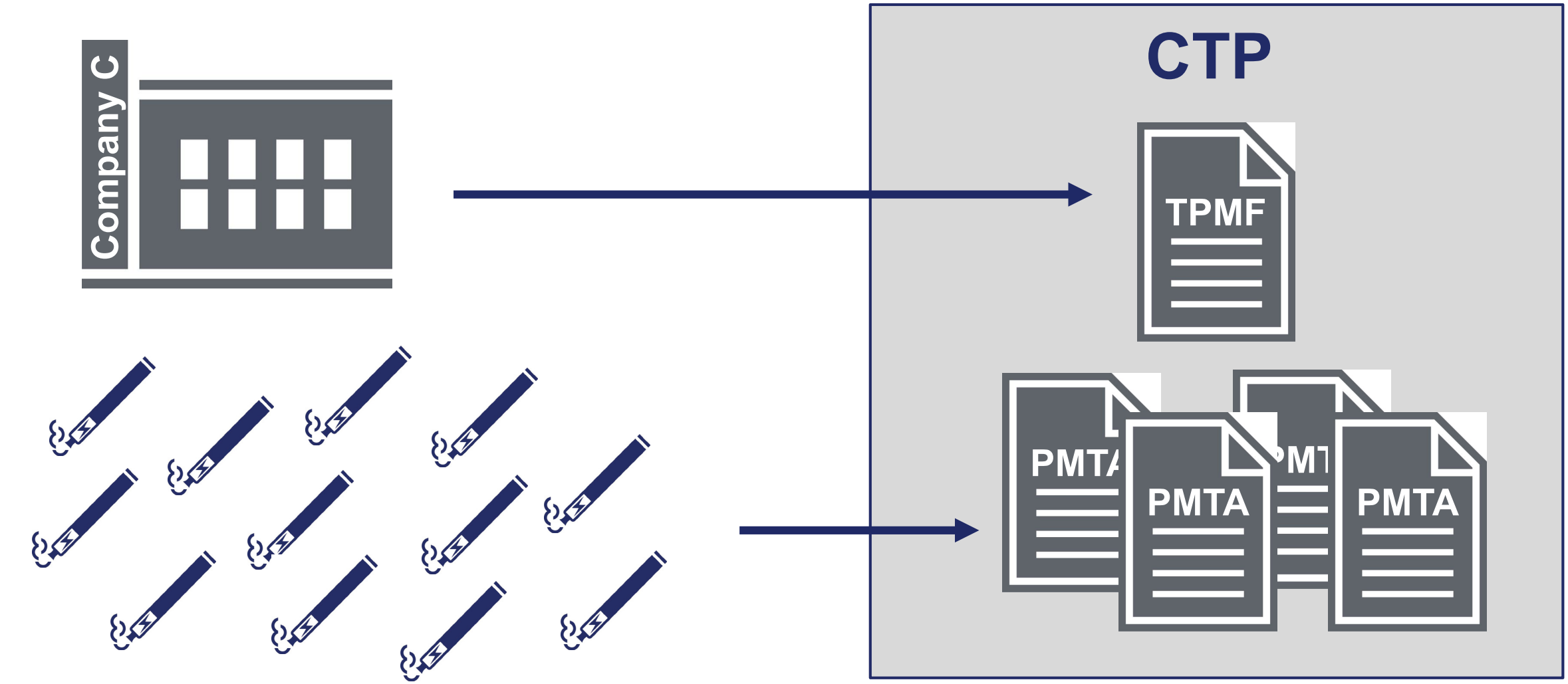


OVERVIEW

- The TPMF program mutually benefits TPMF owners, who can reference their own master file rather than submitting the information separately for multiple submissions.

- By allowing FDA to keep certain information on file in a TPMF, it streamlines, simplifies, and potentially reduces associated costs and time related to administrative work because a company would not need to resubmit data for future applications, thus easing the application burden.

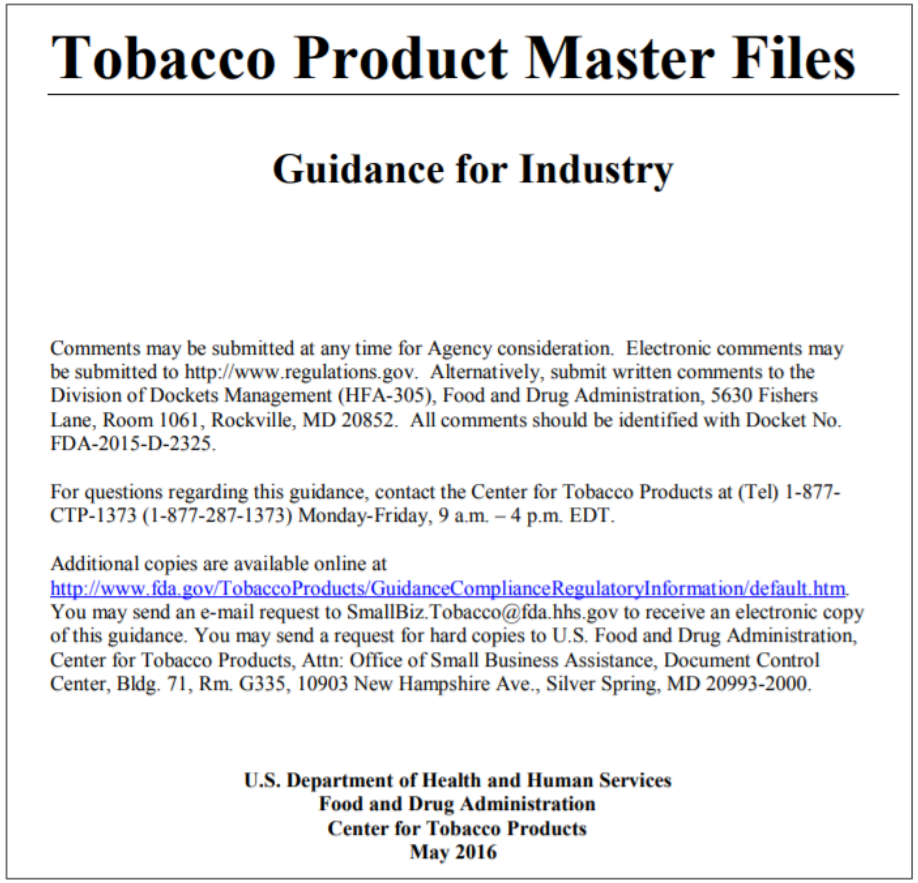
OVERVIEW



OVERVIEW: TPMF GUIDANCE

- FDA published a Tobacco Product Master Files Guidance for Industry in May 2016.

- The guidance document includes:
  - How to establish a master file
  - Considerations for TPMF owners in maintaining TPMF submissions
  - How other persons can use a TPMF
  - FDA's role



Tobacco Product Master Files

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2015-D-2325.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
May 2016

KEY TERMS

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Term	Description
TPMF Owner	An entity that owns the information contained within the TPMF.
Authorized Representative	A person who is authorized to represent and communicate to CTP on behalf the owner, and is able to make decisions regarding the TPMF (e.g., grant or rescind authorizations to the TPMF).
Authorized Party	A person authorized to reference a TPMF and obtains a LOA from the TPMF owner.
Letter of Authorization (LOA)	A document prepared by the TPMF owner or authorized representative, that grants a person authorization to reference a TPMF. The LOA should identify limitations to the authorization.

HOW TO ESTABLISH A TPMF

HOW TO ESTABLISH A TPMF: HOW TO ORGANIZE

- Currently, there are no requirements for structure of a TPMF. CTP recommends the TPMF be organized in a logical manner.

- The CTP Electronic Submission File Formats and Specifications, which can be found on the CTP website, provides a recommended table of contents format and a folder/file structure for submissions to CTP, which include TPMFs.

HOW TO ESTABLISH A TPMF: WHAT TO SUBMIT

Administrative	Content

• Module 1:
  ○ Cover Letter
  ○ Table of Contents
  ○ List of Authorized Representatives
  ○ List of Authorized Parties
  ▪ Limitations to each authorization
	• Examples:
	  ○ Module 3:
	  ▪ Product Design and Specification
	  ▪ Ingredients, Additives, and Constituents
	  ○ Module 4:
	  ▪ Nonclinical Behavioral Studies
	  ▪ Nonclinical Study Model or Analysis
	  ○ Module 5:
	  ▪ Abuse Liability Study (Human)
	  ▪ Actual Use Study

HOW TO ESTABLISH A TPMF: WHERE TO SUBMIT

- CTP is encouraging regulatory correspondence electronically via the CTP Portal.
- Electronic submission is generally available 24 hours a day, seven days a week.

HOW TO ESTABLISH A TPMF: COVER LETTER

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Request to Establish a CTP Tobacco Product Master File (TPMF)

Dear FDA CTP Staff,

Company B would like to establish a TPMF for our rolling paper ingredients. We have manufacture three different kinds of rolling paper: Rolling Paper X, Rolling Paper Y, and Rolling Paper Z.

Administrative Information:

TPMF Owner	Company B
Company Address	123 Road Lane Washington, D.C. 11111
Authorized Point of Contact	Sharyn Kiser, Vice President
Phone Number	(333) 333-3333
E-Mail Address	Sharyn@Kiser.com

Company B grants the following companies authorization to reference our TPMF:

Authorized Party Name	Contact Information	Limitations to Authorization
Company A	Jessica Miller, Vice President 456 Street Court Washington, D.C. 11111 Jessica@Miller.com (222) 222-2222	Authorization to reference Rolling Paper X in Section A.
Company C	Sarah Jones, Vice President 789 Avenue Boulevard Washington, D.C. 11111 Sarah@Jones.com (444) 444-4444	Authorization to reference Rolling Paper Y in Section B.

We have provided letters of authorization to Companies A and C to include in their premarket tobacco product applications.

The information contained in the TPMF contains trade secret and confidential commercial information which is protected from disclosure under 21 CFR 20.61. No information in our TPMF will be provided to any unauthorized persons without written consent.

Please let me know if you have any questions.

Sincerely,

Sharyn Kiser
Vice President, Company B

HOW TO ESTABLISH A TPMF: LOA

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Letter of Authorization for Company A

Dear FDA CTP Staff,

Company B authorizes Company A to incorporate by reference information in our TPMF, MF1234567, for their premarket tobacco product applications. Company A is limited to reference only Rolling Paper X located in Section A.

Authorized Party Information:

Authorized Party Name	Contact Information	Limitations to Authorization
Company A	Jessica Miller, Vice President 456 Street Court Washington, D.C. 11111 Jessica@Miller.com (222) 222-2222	Authorization to reference Rolling Paper X in Section A.

The information contained in MF1234567 contains trade secret and confidential commercial information which is protected from disclosure under 21 CFR 20.61. No information in our TPMF will be provided to any unauthorized persons without written consent.

Please let me know if you have any questions.

Sincerely,

Sharyn Kiser
Vice President, Company B

HOW TO ESTABLISH A TPMF: FDA PROCESS

- ✓ Is there a cover letter?
- ✓ Is the cover letter signed by the TPMF owner?
- ✓ Is the submission a request to establish a TPMF with CTP?
- ✓ Does the submission support submissions to CTP (e.g., premarket tobacco product applications)?
- ✓ Does the submission contain contact information for the TPMF owner?
- ✓ If submitted by an authorized representative, does the submission contain the TPMF owner's authorization (e.g., on TPMF owner's letterhead)?
- ✓ If submitted by a foreign submitter, does the submission identify an authorized U.S. agent and contact information?

TPMF Acknowledgement Letter

HOW TO AMEND A TPMF

HOW TO AMEND A TPMF

- A TPMF can be amended at any time

- CTP recommends Owners include:
  - Cover letter
  - Updated table of contents
  - Historical listing of what information has changed within the TPMF
  - Information that is to be amended in the TPMF

HOW TO REFERENCE A TPMF

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- CTP recommends applicants include:
  - A notation in the cover letter that the application is referencing a TPMF and include the TPMF's STN
  - If possible, where the information being referenced is located in the TPMF
  - A valid LOA to reference the TPMF

- If there are any questions about the content of the TPMF, the authorized party should contact the Owner.

HOW A TPMF IS REVIEWED

HOW A TPMF IS REVIEWED

1. CTP receives a submission (e.g., PMTA) that references a TPMF.

2. CTP verifies that the applicant is authorized to reference the TPMF and the extent of the applicant's authorization.

3. CTP begins scientific review of both the application and TPMF. This review, based on the reference, will likely result in CTP finding the information in the TPMF adequate or inadequate.

HOW A TPMF IS REVIEWED: ADEQUATE

4. CTP determines the TPMF content is adequate.

5. CTP continues scientific review of the application.

6. Because there are no deficiencies in the TPMF information that was referenced and reviewed, CTP does not send a letter to the TPMF owner.

HOW A TPMF IS REVIEWED: INADEQUATE

4. CTP determines the TPMF content is deficient.

5. CTP sends letters to both the TPMF owner and applicant.
   - The letter to the TPMF owner will detail specific deficiencies and a request to respond within a requested timeframe to amend the TPMF.
   - The letter to the applicant will simply cite that deficiencies were found in the TPMF which have been communicated to the TPMF owner.

HOW A TPMF IS REVIEWED: IMPORTANT NOTES

- The authorized party is solely responsible for ensuring that their premarket application and supporting documents (e.g., TPMF) is adequate to support all statutory requirements.

- If the TPMF owner does not respond, or fails to provide documents necessary to support a referencing submission, the referencing submission likely will not move forward. In the case of an application seeking an order, this will result in a negative action.

- We encourage the authorized party and TPMF owner to communicate and coordinate their responses to CTP's letters so that CTP's comments are adequately addressed in the requested timeframe.

KEY TAKE HOME POINTS

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- TPMFs are a beneficial tool for manufacturers, component suppliers, ingredient suppliers, and researchers, and can assist the tobacco product submission process
- The applicant/authorized party, at any point in time, does not see or have access to the TPMF content
- A TPMF is reviewed when referenced by another submission
- CTP reviews the TPMF in the scope and context of the referenced submission
- Timelines for TPMF review depend on the referencing submission

THE END

Questions?

- Ask questions during the panel discussion
- Contact your regulatory health project manager
- Contact CTP's Call Center, Office of Small Business, Office of the Ombudsman
- Email AskCTP@fda.hhs.gov