TOBACCO PRODUCT MASTER FILES (TPMFS)

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AGENDA

- Overview
- Key Terms
- Type of Information to Include in a TPMF
- Establishment Process **Establishment**
- Scientific Review Process **Scientific Review** **Determination**
- Closure Process **Closure**
- Best Practices for TPMF Owners
- 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.

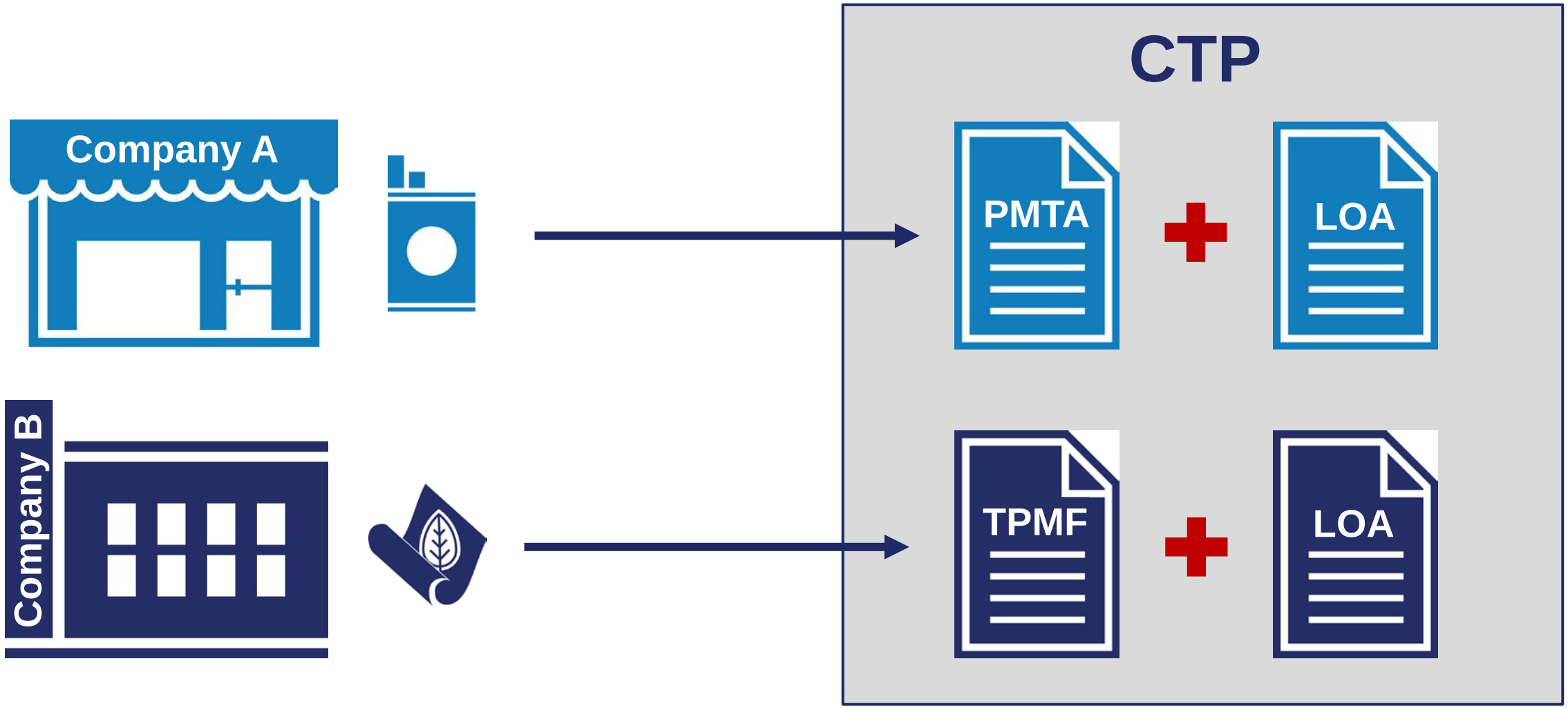
- TPMFs are a beneficial tool for manufacturers, component suppliers, ingredient suppliers, and researchers, and can assist the tobacco product submission process.

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

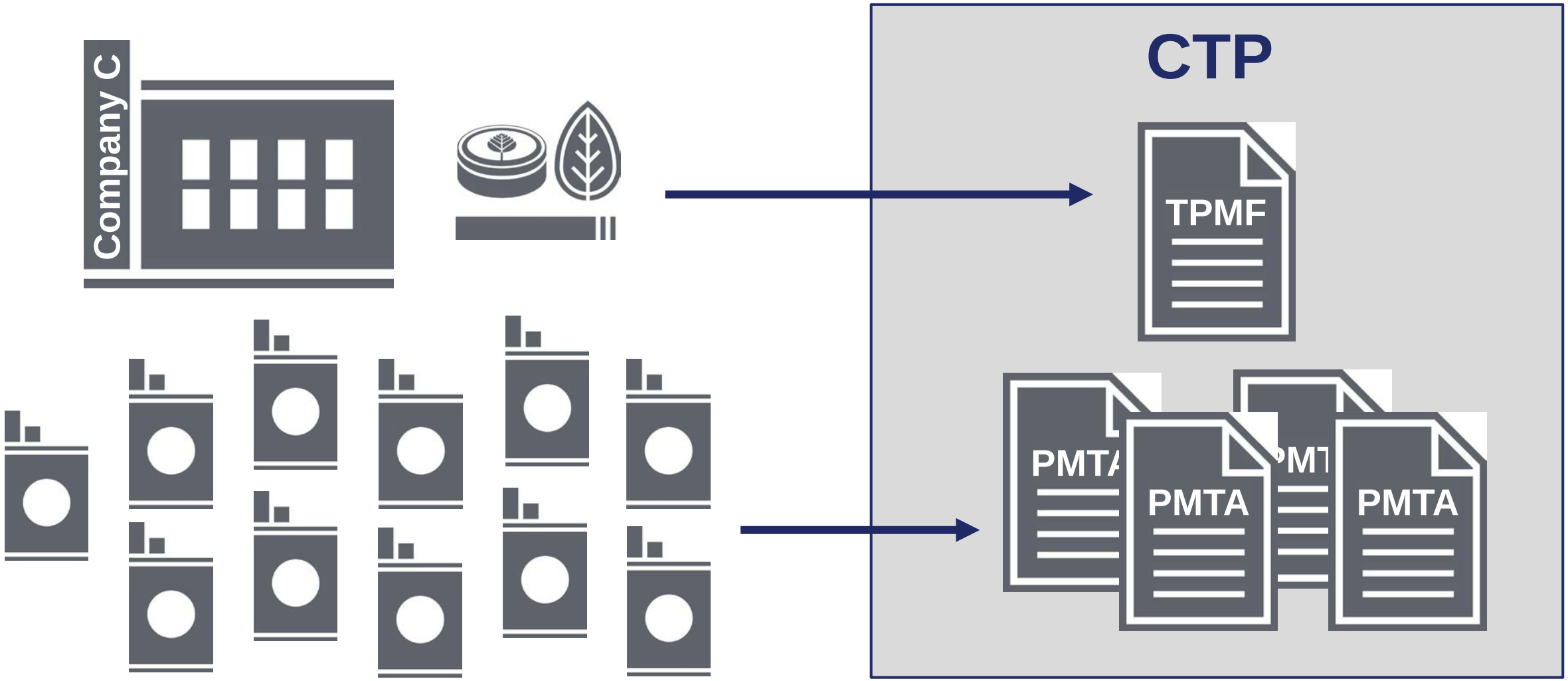


OVERVIEW

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

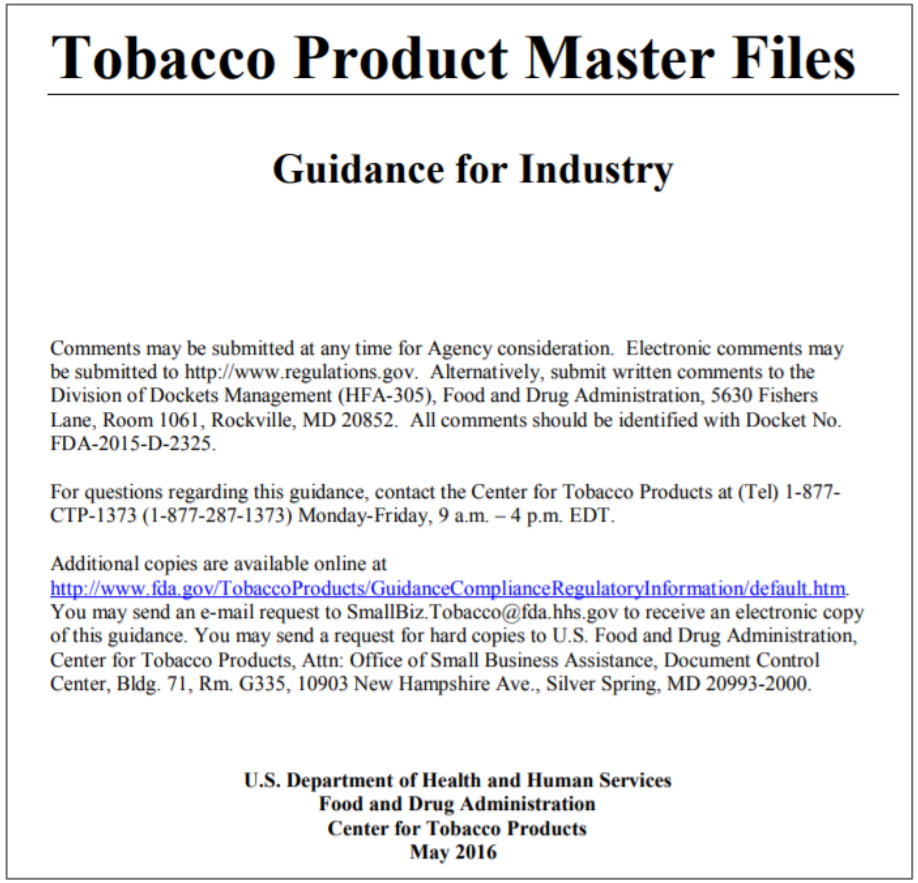
- By allowing FDA to keep certain information on file in a TPMF, it streamlines, simplifies, and potentially reduces associated costs and time related to administrative work because a company would not need to resubmit data for future applications, thus easing the application burden.

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
    - What to submit
    - Where to submit
  - Considerations for TPMF owners in maintaining TPMF submissions
    - Updates to information
    - Closure of a TPMF
  - How other persons can use a TPMF
  - FDA's role
    - Review of a TPMF
    - FDA initiation of TPMF closure



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.

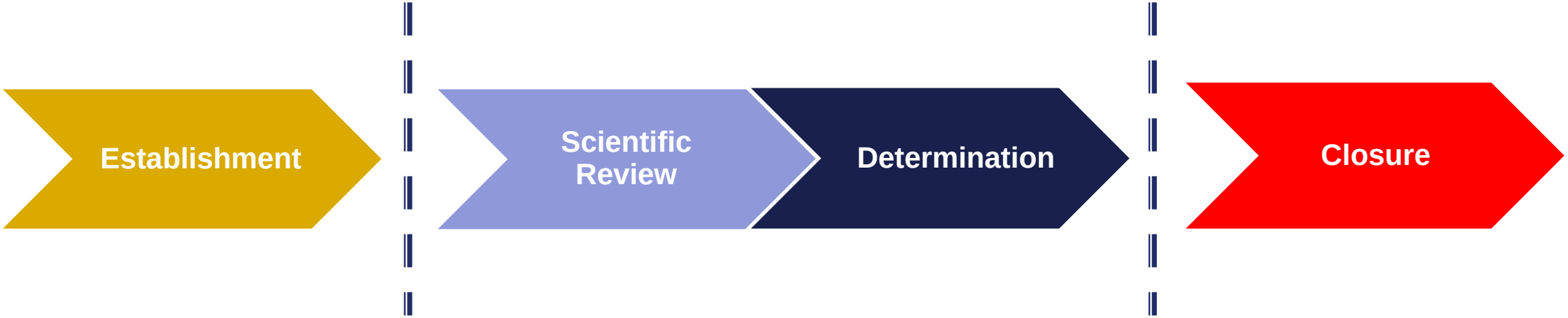
Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug 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

OVERVIEW: TPMF WEBINAR

- Webinar on Using a TPMF for Ingredient Listing Submissions in September 2018.
- The webinar includes:
  - Examples of ingredient listing scenarios that a TPMF can address
  - How to cross-reference TPMFs for ingredient submissions

OVERVIEW: TPMF PROCESS



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.

TYPE OF INFORMATION TO INCLUDE IN A TPMF

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Administrative Information	Content Information

• Cover Letter
• Table of Contents
• List of Authorized Representatives
• List of Authorized Parties
  o Limitations to each authorization
	• Examples:
	  o Tobacco product information (tobacco blend, HPHC methods, design parameter information, ingredient listing)
	  o Manufacturing and processing data
	  o Research findings (clinical and nonclinical)
	  o Other

TYPE OF INFORMATION TO INCLUDE IN 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

TYPE OF INFORMATION TO INCLUDE IN 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

ESTABLISHMENT PROCESS

Establishment

ESTABLISHMENT 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 submission for tobacco products)?
- ✓ 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

Establishment

SCIENTIFIC REVIEW PROCESS

SCIENTIFIC REVIEW PROCESS

- CTP does not intend to conduct a scientific review of a TPMF at the time of its submission.

- CTP intends to conduct a scientific review of the TPMF only when the TPMF is referenced in an authorized party's submission to CTP. This is because different submissions may have different information content needs.

SCIENTIFIC REVIEW PROCESS: EXAMPLE OF DIFFERENT TPMF INFORMATION CONTENT NEEDS

Ingredient Listing	PMTA
• product identification • ingredient identification • part to which the ingredient is added • ingredient quantity	• components • ingredients • additives • properties • principle of operation • methods used in the manufacture and processing • testing data

Scientific Review

SCIENTIFIC REVIEW PROCESS

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.
   - It is recommended that the applicant provide an LOA to reference the TPMF in its application; in the application's cover letter, the STN of the TPMF being referenced; and if possible, where the information being referenced is located in the TPMF.

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.

Scientific Review

SCIENTIFIC REVIEW PROCESS: 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 a reviewed, CTP does not send a letter to the TPMF owner.

Determination: Adequate

SCIENTIFIC REVIEW PROCESS: 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.

Determination: Inadequate

SCIENTIFIC REVIEW PROCESS: INADEQUATE

6. CTP continues scientific review of the application and amended TPMF once the response date to the applicant's letter passes or CTP receives a complete response.

7. CTP will issue an appropriate letter consistent with the application process.

Determination: Inadequate

SCIENTIFIC REVIEW PROCESS

- 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.

CLOSURE PROCESS

CLOSURE PROCESS

- If a TPMF owner wishes to close its TPMF, the TPMF owner should notify CTP in writing and include the reason for requesting closure of the file and the date the TPMF should be closed.

- It is recommended that the TPMF owner notify all persons currently authorized to reference the TPMF of the closure, as once closed, the TPMF will no longer be available for reference by an authorized party and CTP will no longer review the content when referenced in a submission.

Closure

CLOSURE PROCESS

- CTP intends to begin a closure process if the TPMF has not been referenced in a three-year period and the TPMF has not been updated during this time. This may occur for example, if the TPMF owner is not responsive to CTP's letters requesting information for a referenced submission.

- Prior to CTP-initiated closure of a TPMF, CTP intends to issue a notification letter to the TPMF owner of the intent to close.

- Within this notification letter, a timeframe will be provided for response. The TPMF owner may choose keep its TPMF open. CTP encourages the owner to respond within the timeframe with its intent. If there is no response to the notification letter, CTP will move forward with TPMF closure.

BEST PRACTICES FOR TPMF OWNERS

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In general, TPMF owners are responsible for:

1. Serving as a point of contact for the TPMF
2. Notifying CTP and authorized parties of any changes in the TPMF
3. Responding to deficiency letters

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