DEPARTMENT OF HEAL TH AND HUMAN SERVICES
Food and Drug Administration

Premarket Tobacco Product Application (PMTA) Submission

Form Approved: OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on page 22

SECTION I - APPLICANT IDENTIFICATION

Applicant Information

Name of Applicant (Provide only either a person's name or an organization's name)	First Name	M.I.	Last Name	Date of Submission

Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

Organization name

Company Headquarters' FDA-assigned Facility Establishment Identifier (FEI) Number	Company Headquarters' D&B DUNS® Number

Applicant Address and Contact Information	Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province, or Territory	Country	ZIP or Postal Code

Contact Name (Optional, for use if Applicant is an Organization)	First Name	M.I.	Last Name

Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

Telephone *(Include Country Code if applicable)*	FAX	Email Address

Organization Name and Address Information (Optional, for use if Applicant is an Individual)	Organization name

Primary Address (Street Address, P.O. Box) ☐ Select for same address as Applicant

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province, or Territory	Country	ZIP or Postal Code

Authorized Representative Information *(Responsible official authorized to represent the applicant)*

Name of Authorized Representative (Provide only either a person's name or an organization's name)	First Name	M.I.	Last Name

Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

Organization name

Authorized Representative Address and Contact Information	Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province, or Territory	Country	ZIP or Postal Code

Contact Name (Optional, for use if Authorized Representative is an Organization)	First Name	M.I.	Last Name

Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

Telephone *(Include Country Code if applicable)*	FAX	Email Address

Organization name and Address Information (Optional, for use if Authorized Representative is an Individual)	Organization name

Primary Address (Street Address, P.O. Box)	☐ Select for same address as Authorized Representative

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province, or Territory	Country	ZIP or Postal Code

Manufacturer Information *(if different from Applicant)*

Organization name

Company Headquarters' FDA-assigned Facility Establishment Identifier (FEI) Number	Company Headquarters' D&B DUNS® Number

Organization Address and Contact Information	Street Address (Physical Location)

Address 2 (Apt, Suite, Bldg., etc.)	City

State, Province, or Territory	Country	ZIP or Postal Code

U.S. Agent Information *(For foreign firm where Authorized Representative does not reside in the U.S.)*

Name of U.S. Agent (Provide only either a person's name or an organization's name)	First Name	M.I.	Last Name

Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

Organization name

U.S. Agent Address and Contact Information	Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province or Territory	Country United States	ZIP or Postal Code

Contact Name (Optional, for use if U.S. Agent is an Organization)	First Name	M.I.	Last Name

Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

Telephone (Include Country Code if applicable)	FAX	Email Address

Organization name and Address Information (Optional, for use if U.S. Agent is an Individual)	Organization name

Primary Address (Street Address, P.O. Box)

☐ Select for same address as U.S. Agent

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province, or Territory	Country	ZIP or Postal Code

Alternate Point of Contact *(Attach a separate sheet to list all alternate points of Contact)*

☐ Applicant	☐ Authorized Representative	☐ Other, Regulatory
☐ Manufacturer (Other than Applicant)	☐ U.S. Agent	☐ Other, Technical

Prefix *(e.g., Mr., Ms., Dr.)*	First Name	M.I.	Last Name

Professional Suffix (e.g., MD, Ph.D.)	Generational Suffix *(e.g., Jr., III)*	Position Title

Alternate Point of Contact Address and Contact Information	Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)	City

State, Province or Territory	Country	ZIP or Postal Code

Telephone (Include Country Code if applicable)	FAX	Email Address

SECTION II - NEW TOBACCO PRODUCT INFORMATION

Complete this section for each individual new tobacco product.

☐ Check here if you are submitting a co-packaged product.

For a co-packaged tobacco product, please complete Section III for each new tobacco product included within the co-package.

New Tobacco Product Name (Brand/Sub-Brand)

Product Category/Sub-Category:

☐ **Electronic Nicotine Delivery System (Vapes)**
- ☐ E-Liquid, Open
- ☐ E-Liquid, Closed
- ☐ E-Cigarette, Closed
- ☐ E-Cigarette, Open
- ☐ ENDS Component
- ☐ Other _____

☐ **Pipe Tobacco Products**
- ☐ Pipe
- ☐ Pipe Tobacco Filler
- ☐ Pipe Component
- ☐ Other _____

☐ **Smokeless Tobacco Products**
- ☐ Moist Snuff, Loose
- ☐ Moist Snuff, Portioned
- ☐ Snus, Loose
- ☐ Snus, Portioned
- ☐ Dry Snuff, Loose
- ☐ Dissolvable
- ☐ Chewing Tobacco, Loose
- ☐ Chewing Tobacco, Portioned
- ☐ Other _____

☐ **Heated Tobacco Products (HTP)**
- ☐ Closed HTP
- ☐ Open HTP
- ☐ HTP Consumable
- ☐ HTP Component
- ☐ Other _____

☐ **Roll-Your-Own Tobacco Products**
- ☐ Roll Your Own Tobacco Filler
- ☐ Rolling Paper
- ☐ Cigarette Tube, Filtered
- ☐ Cigarette Tube, Non-filtered
- ☐ Filter
- ☐ Paper Tip
- ☐ Other _____

☐ **Cigarettes**
- ☐ Filtered
- ☐ Non-filtered
- ☐ Other _____

☐ **Waterpipe Tobacco Products**
- ☐ Waterpipe
- ☐ Waterpipe Tobacco Filler
- ☐ Waterpipe Heat Source
- ☐ Waterpipe Component
- ☐ Other _____

☐ **Cigars**
- ☐ Filtered, Sheet-Wrapped
- ☐ Unfiltered, Sheet-Wrapped
- ☐ Unfiltered, Leaf-Wrapped
- ☐ Cigar Component
- ☐ Cigar Tobacco Filler
- ☐ Other _____

☐ **Other** _____

☐ **Other** _____

Unique Identification of New Tobacco Products

Refer to Section VIII, Appendix B, to determine the specific properties that need to be reported based on the category and sub-category of the new tobacco product. Provide data for each required property by filling in the table below, and provide the target value for the new tobacco products (s). Attach additional tables to this section as needed.

Refer to section VIII, Appendix A, for examples of how a new tobacco product should be uniquely identified.

In the following table, please enter both the name of the new tobacco product(s) and the properties of each product below its name.

Product Identification		
	New Tobacco Product	
Name:		
Properties	1	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	
	10	
	11	
	12	
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SECTION III - SUBMISSION INFORMATION

Specify submission type (*Select one submission type per form*)

(*Select one submission type per form)* ☐ Standard PMTA ☐ Resubmission ☐ Supplemental PMTA

(check only one) ☐ This PMTA is for an individual new tobacco product ☐ This is a group of PMTAs covering multiple new tobacco products

Cross-referenced Content: Identify Cross-referenced Submission Type as one of the following: Standard PMTA, Tobaccco Product Master File, or Modified Risk Tobacco Product Application (MRTPA)

New Tobacco Product Name (Provide product name if this Cross-referenced content is relevant to a specific product in your bundled submission)	
☐ Select if this Cross-referenced Content is relevant to all bundled products	
Cross-referenced Submission Type	Cross-referenced Submission STN

Related Submissions: List the FDA submission tracking numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable

New Tobacco Product Name (Provide product name if this Related Submission is relevant to a specific product)	
☐ Select if this Related Submission is relevant to all bundled products	
Related Submission Type	Related Submission STN

Formal Meetings Held with FDA pertaining to this tobacco product *(For each meeting, as needed, enter the STN number and meeting held date.)*

New Tobacco Product Name (*Provide product name if meeting is relevant to a specific product*)	Select if this Meeting is relevant to all bundled products	Submission STN	Meeting Held Date
	☐		
	☐		
	☐		
	☐		
	☐		

For products that have been previously commercially marketed in the U.S., please list the date(s) during which the tobacco product was marketed.

SECTION IV - APPLICATION CONTENTS

This application contains the following items (Select all that apply)

Administrative

- ☐ Cover Letter
- ☐ Comprehensive Index*
- ☐ Table of Contents*
- ☐ English* Translations for Non-English Information
- ☐ Request for FDA to refer PMTA to Tobacco Product Science Advisory Committee (TPSAC)

Labeling and Marketing Plans

- ☐ Specimens of all Proposed Labelling*
- ☐ Description of Marketing Plans*

Inspections

- ☐ Location and Contact Information for Each Location Subject to Potential Inspection

Scientific Content (see Appendix C for examples and description)

- ☐ General Information*
- ☐ Descriptive Information*
- ☐ Product Samples**
- ☐ Statement of Compliance with 21 CFR part 25*
- ☐ Summary*
- ☐ Product Formulation*
- ☐ Manufacturing*
- ☐ Literature Search*
- ☐ Organized References
- ☐ Health Risk Investigations*
- ☐ Study Reports*
- ☐ Other (Specify below)

_____

*Required content and format as per §1114.7 (Standard PMTA), 1114.15 (Supplemental PMTA) and 1114.17 (Resubmission).
**FDA generally expects that product samples will be a required part of a PMTA and that an applicant should be prepared to submit them in accordance with FDA instructions within 30 days after submitting a PMTA; however there may be situations in which sample submission may not be necessary (see Appendix C for additional information)

SECTION V - MANUFACTURING/PACKAGING/STERILIZATION SITES RELATING TO A SUBMISSION
(Add additional manufacturing/packaging/sterilization sites as needed)

Company/Institution Name			
☐ Manufacturer ☐ Contract Manufacturer ☐ Repacker/ Relabeler			
Company Headquarters' FDA-assigned Facility Establishment Identifier (FEI) Number		Company Headquarters' D&B DUNS® Number	
Division Name (If applicable)		Primary Address (Street Address, P.O. Box)	
City	State, Province or Territory	ZIP or Postal Code	Country
Telephone (Include Country Code if applicable)		FAX	

Contact Name	First Name	M.I.	Last Name
Prefix *(e.g., Mr., Ms., Dr.)*	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title

The Manufacturing/Packaging/Sterilization Site is ready for inspection ☐ Yes ☐ No

Section VI - Statements of Compliance with the Federal Food, Drug and Cosmetic (FD&C) Act

☐ Includes a brief description of how the PMTA satisfies content requirements of section 910(b)(1) of the FD&C Act (specify in the table of contents where the brief description is located)

☐ Includes a brief description of how marketing the new tobacco product would be appropriate for the protection of public health as determined with respect to the population as a whole, including users and non-users of the tobacco product, and taking into account the following (specify in the table of contents where the brief description is located)

a. The increased or decreased likelihood that existing users of tobacco products will stop using such products and;

b. The increased or decreased likelihood that those who do not use tobacco products will start using such products

Section VII - Certification Statements

The application must contain the following certifications, as appropriate for the specific type of PMTA, with the appropriate information inserted, as described in each parenthetical, signed by an authorized representative of the applicant.

1. Certification statement for standard PMTAs
2. Modified tobacco product certification for supplemental PMTAs
3. Same product certification for resubmissions
4. Different product certification for resubmissions
5. Certification Statement of Financial Interests and Arrangements by Clinical Investigators

1. General Application Certification Statement for all applications:*

I, (name of responsible official) , on behalf of the applicant, (applicant name) , hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that records remain readily available to FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties."

Signature	Date

2. Modified tobacco product certification for supplemental PMTAs.*

"I *(name of responsible official)* _____, on behalf of *(name of applicant)* _____, certify that *(new tobacco product name)* _____, has a different (describe each modification to the product) _____ than *(name of original tobacco product)* described in (STN of PMTA for the original product) but is otherwise identical to *(name of original tobacco product)* .

I certify that *(name of applicant)* understands this means there is no other modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product. I also certify that *(name of applicant)* will maintain all records that substantiate the accuracy of this application, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties."

Signature	Date

3. Same tobacco product certification for resubmission*

"I *(name of responsible official)* , on behalf of *(name of applicant)* , certify that this submission for (new tobacco product name) responds to all deficiencies outlined in the marketing denial order issued in response to (STN of the previously submitted PMTA) and the new tobacco product described herein is identical to the product described in the previously submitted PMTA. I certify that (name of applicant) understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature. I also certify that (name of applicant) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties."

Signature	Date

4. Different tobacco product certification for resubmission*

"I, (name of responsible official) , on behalf of (name of applicant) , certify that this submission for (new tobacco product name) responds to all deficiencies outlined in the marketing denial order issued in response to (STN of the previously submitted PMTA) and the new tobacco product described herein has a different (describe each modification to the product) than (name of original tobacco product) described in (STN of the previously submitted PMTA) but is otherwise identical to (name of original tobacco product) described in (STN of the previously submitted PMTA) . I certify that (name of applicant) understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product, except for the (describe each modification to the tobacco product) . I also certify that (name of applicant) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties."

Signature	Date

5. Financial Interest and Arrangements of Clinical Investigators Certification Statement*:

"I, (name of responsible official), on behalf of (name of company) , certify that there are no financial conflicts of interest or have included documentation fully disclosing any potential financial conflicts of interest required by 21 CFR § 1114.7(k)(3)(ii).

☐ No, there are no financial conflicts of interest

☐ Yes, there are financial conflicts of interest and documentation is provided (please specify in the table of contents where the documentation is located)

Signature	Date

*Required certification statement as per proposed§ 1114.7 (Standard PMTA), 1114.15 (Supplemental PMTA) and 1114.17 (Resubmission).

SECTION VIII – APPENDICES

Appendix A: New Tobacco Product Details

Use the tables below as examples of how to format and capture data necessary to uniquely identify products in Section II.

Below is an example of a single new tobacco product. Refer to Appendix B for the list of properties necessary to uniquely identify a product depending upon the category and sub-category to which that product belongs.

Unique Product Identification	
Properties *(Inserted on form)*	***New Tobacco Product*** *Name: Product A*
Package Type	Box
Product Quantity	20 Cigarettes per box
Diameter	100 mm
Length	6 mm
Ventilation	None
Characterizing Flavor	None
Additional Properties	N/A

Below is an example of multiple new tobacco products.

Unique Product Identification			
Properties *(Inserted on form)*	***New Product 1*** *Name: Product A* / *STN: N/A*	***New Product 2*** *Name: Product A* / *STN: N/A*	***New Product 3*** *Name: Product A* / *STN: N/A*
Package Type	Box	Box	Box
Product Quantity	20 Cigarettes per box	20 Cigarettes per box	20 Cigarettes per box
Diameter	100 mm	100 mm	100 mm
Length	6 mm	6 mm	6 mm
Ventilation	None	None	None
Characterizing Flavor	None	None	None
Additional Properties	N/A	N/A	N/A

Below is an example of new tobacco products that are co-packaged together as part of one submission.

Name of Co-Package: Variety Pack A/B	
Unique Product Identification	
Co-Packaged Categories and Unique Identification Properties	***New Tobacco Product(s)***
Category: Roll-Your-Own Sub-Category: Roll-Your-Own Tobacco Filler	*Name: Product A*
Package Type	Bag
Package Quantity	100 g
Characterizing Flavor	None
Additional Properties	Re-sealable Bag
Category: Roll-Your-Own Sub-Category: Roll-Your-Own Rolling Paper	*Name: Product B*
Package Type	Booklet
Package Quantity	100 sheets
Length	100 mm
Width	56 mm
Characterizing Flavor	None
Additional Properties	Black Box

Appendix B: Properties Needed to Uniquely Identify the Tobacco Product, by Category and Subcategory

The following are tables outlining all necessary properties to be captured for each category and sub-category of tobacco products. An "X" denotes a required property for that given sub-category.

Reference the charts below for completing tables necessary for Section IV.

Cigarette Tobacco Products	
Properties	***Sub-Categories***
	All Cigarettes
Package Type	X
Product Quantity	X
Diameter	X
Length	X
Ventilation	X *(except non-filtered)*
Characterizing Flavor	X
Additional Properties (if applicable)	X

Roll-Your-Own Tobacco Products							
Properties	***Sub-Categories***						
	Tobacco Filler	*Rolling Paper*	*Filtered Cigarette Tube*	*Non-Filtered Cigarette Tube*	*Filter*	*Paper Tip*	*Other*
Package Type	X	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X	X
Diameter			X	X	X		
Length		X	X	X	X	X	
Ventilation			X				
Width		X				X	
Characterizing Flavor	X	X	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X	X	X

Cigar						
Properties	***Sub-Categories***					
	Component	*Filtered Sheet-Wrapped*	*Unfiltered Sheet-Wrapped*	*Leaf-Wrapped*	*Tobacco Filler*	*Other*
Package Type	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X
Length		X	X	X		
Diameter		X	X	X		
Ventilation		X				
Wrapper Material				X		
Tip			X			
Characterizing Flavor	X	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X	X

Smokeless Tobacco Products									
Properties	***Sub-Categories***								
	Loose Moist Snuff	*Portioned Moist Snuff*	*Loose Snus*	*Portioned Snus*	*Loose Dry Snuff*	*Dissolvable*	*Loose Chewing*	*Portioned Chewing*	*Other*
Package Type	X	X	X	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X	X	X	X
Portion Count		X		X		X		X	
Portion Length		X		X		X		X	
Portion Width		X		X		X		X	
Portion Mass		X		X		X		X	
Portion Thickness		X		X		X		X	
Characterizing Flavor	X	X	X	X	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X	X	X	X	X

Electronic Nicotine Delivery System (Vapes)						
Properties	***Sub-Categories***					
	Component	*Open E-Liquid*	*Closed E-Liquid*	*Open E-Cigarette*	*Closed E-Cigarette*	*Other*
Package Type	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X
Length				X	X	
Diameter				X	X	
E-Liquid Volume		X	X	X	X	
Nicotine Concentration		X	X		X	
PG/VG Ratio		X	X		X	
Battery Capacity				X	X	
Wattage				X	X	
Characterizing Flavor	X	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X	X

Heated Tobacco Products (HTP)					
Properties	***Sub-Categories***				
	Component	*Closed HTP*	*Open HTP*	*Consumable*	*Other*
Package Type	X	X	X	X	X
Product Quantity	X	X	X	X	X
Length		X	X	X	
Diameter		X	X	X	
Ventilation				X	
Wattage		X	X		
Battery Capacity		X	X	X	
Characterizing Flavor	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X

Pipe Tobacco Products				
Properties	***Sub-Categories***			
	Component	*Pipe*	*Tobacco Filler*	*Other*
Package Type	X	X	X	X
Product Quantity	X	X	X	X
Length		X		
Diameter		X		
Characterizing Flavor	X	X	X	X
Tobacco Cut Size			X	
Additional Properties (if applicable)	X	X	X	X

Waterpipe Tobacco Products					
Properties	***Sub-Categories***				
	Component	*Waterpipe*	*Heat Source*	*Tobacco Filler*	*Other*
Package Type	X	X	X	X	X
Product Quantity	X	X	X	X	X
Width		X			
Portion Count			X		
Portion Length			X		
Portion Width			X		
Portion Mass			X		
Portion Thickness			X		
Number of Hoses		X			
Source(s) of Energy			X		
Characterizing Flavor	X	X	X	X	X
Height		X			
Diameter		X			
Additional Properties (if applicable)	X	X	X	X	X

Other Tobacco Products	
Properties	***Other Sub-Categories***
Package Type	X
Product Quantity	X
Characterizing Flavor	X
Additional Properties (if applicable)	X

APPENDIX C
INSTRUCTIONS FOR COMPLETION OF PMTA FORM

This form and the instructions for use are solely intended to provide the applicant an organized format to supply information required for submission of a Premarket Tobacco Product Application (PMTA)

Section I - Applicant Identification

1. Provide applicant name (means any person that submits a premarket tobacco product application to receive a marketing granted order for a new tobacco product)
2. Provide submission date of application
3. Provide name and address information of manufacturer (if different from applicant)
4. Provide the FDA Establishment Identifier (if applicable)
5. Provide the DUNS Number of headquarters (if applicable)
6. Provide applicant address and contact information
7. Provide name of Authorized Representative (responsible official authorized to represent the applicant)
8. Provide Authorized Representative contact information
9. Provide name of U.S. Agent
10. Provide U.S. Agent address and contact information
11. Provide name of alternate point of contact
12. Provide alternate point of contact address and contact information

Section II - New Tobacco Product Information (Provide information that uniquely identifies the tobacco product)

13. Provide name of tobacco product (full tobacco product name including brand name/sub-brand name or other commercial name used in commercial distribution)
14. Provide tobacco product category and sub-category
15. Provide tobacco product package type (e.g., can/box/bag)
16. Provide tobacco product quantity
17. Provide co-package information. If an applicant submits an PMTA for a co-packaged tobacco product, the unique identification of this co-packaged product would include the specific items needed to identify each product within the co-package. For example, if the co-package is a pouch of roll-your-own tobacco filler that contains rolling papers inside the pouch, the applicant would identify the tobacco product as a co-packaged product and provide the unique identification for both roll-your-own tobacco filler and rolling papers.
18. Provide tobacco product characterizing flavors applicable to the new tobacco product. If you believe that your tobacco product does not have a characterizing flavor, state "none." For example: Orange and mint can be characterizing flavors
19. Provide tobacco product descriptive properties as required by 21 CFR § 1114.7(c)(3)(iii). For example: The product is a portioned smokeless tobacco product made using a blend of burley and bright tobacco
20. Provide product properties that uniquely identify the tobacco product as set forth in 21 CFR § 1114.7(c)(3)(iii)

Section III - Submission Information (Select the submission type(s) that apply to your application)

21. Standard PMTA 21 CFR § 1114.7

- A standard PMTA is a submission from an applicant seeking a marketing granted order to introduce a new tobacco product into interstate commerce. A standard PMTA contains the full text of the information required by§ 1114.7, except where included by cross reference to a tobacco product master file or a pending modified risk tobacco application for the same product.

22. Resubmission 21 CFR § 1114.17

- A resubmission is an alternative way of submitting an application that meets the requirements of §1114.7 or §1114.15 to seek a marketing granted order for a new tobacco product by providing new information to address the deficiencies outlined in a marketing denial order and cross-referencing applicable content from the denied PMTA. An applicant may submit a resubmission for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order.

23. Supplemental PMTA 21 CFR § 1114.15

- A supplemental PMTA may be submitted by an applicant that is seeking authorization for modifications made to a new tobacco product for which they have already received a marketing granted order. The following are examples of tobacco products modifications that may be appropriate for a supplemental PMTA:
  - Changes in connection type/thread size (e.g., 510)
  - Minor Software Changes not affecting device functionality, such as:
    - Changes to user interface
    - Changes in recording/data capture properties
  - Certain changes to account for improvements in electronics technology or to improve use and convenience (e.g., use of haptics or simplification of device functions like cleaning cycle)
  - Minor changes in e-liquid volume, viscosity or boiling temperature
  - Minor changes in draw resistance
  - Minor changes in air flow rate
  - Changes to coil configuration if number of coils, coil gauge, material, and overall coil resistance remain unchanged
  - Changes to amount of wicking material

24. If you included content in your PMTA by cross-reference to another submission or a master file, provide cross-reference information. See 21 CFR §1114.7(b), § 1114.15(b), or §1114.17(b), as applicable, for restrictions on what may be cross referenced.

25. Provide FDA submission tracking numbers (STN) for all previous related request for the new tobacco products

26. Provide previous meeting dates

27. If the product has previously been commercially marketed in the US, provide the date(s) which the tobacco product was marketed.

Section IV - Application Contents (The application contains the following items)

Administrative

a. Cover Letter
b. Comprehensive Index (required by 21 CFR § 1114.7(b)(1))
c. Table of Contents (required by 21 CFR § 1114.7(b)(1))
d. Written in English or accompanied by an English translation for non-English information (required by 21 CFR § 114.7(b)(1)
e. Optional Request for FDA to Refer PMTA to Tobacco Product Scientific Advisory Committee (required by 21 CFR § 1114.7(c)(5))

Labeling and Marketing Plans

a. Specimens of all proposed labeling (required by 21 CFR § 1114.7(f)(1))
b. Marketing Plans (required by 21 CFR § 1114.7(f)(2))

Inspections

a. Location and contact information for each location subject to potential inspection (required by 21 CFR § 1114.7(k)(3)(vii))

Scientific Content

a. General information (e.g., product name, product category, subcategory and product properties) (required by 21 CFR § 1114.7(c))
b. Descriptive information (required by 21 CFR § 1114.7(d))
c. Product samples (as required by FDA in accordance with 21 CFR § 1114.7(e))
   FDA generally expects that product samples will be a required part of a PMTA and that an applicant should be prepared to submit them in accordance with FDA instructions within 30 days after submitting a PMTA. There may be situations in which sample submission may not be necessary, including, in some circumstances, PMTAs that are resubmitted for the same product after a marketing denial order (such as resubmissions as described in § 1114.17) or PMTAs submitted for modifications to an authorized product where the modifications do not require review of new samples as part of the PMTA evaluation process. Presubmission meetings with FDA may help provide additional information about whether product samples will need to be included in a PMTA; however, in most situations, FDA will only be able to determine the need for product samples after a PMTA is accepted for review.
d. Statement of compliance with 21 CFR part 25 (e.g. Environmental Assessment) (required by 21 CFR § 1114. 7(g))
e. Summary (required by 21 CFR §1114.7(h))
f. Product formulation (e.g., components, ingredients, additives, properties, and principles of operations) (required by 21 CFR § 1114.7(i))
g. Manufacturing (e.g., methods, facilities, controls) (required by 21 CFR § 1114.7(j))
h. Literature Search (required by 21 CFR § 1114.7(k)(2))
   A literature search is a search of available is a search of available documents that includes: 1) clear search objectives 2) a description of methodologies used in the search in detail 3) an identification of relevant documents 4) a formal or informal evaluation of study quality 5) a bibliography of referenced publications.
i. Organized references used to compile information in the submission
j. Health Risk Investigations 21 CFR 1114.7(k)
   Examples of health risk investigations include but not limited to: Toxicological Risk Evaluation, Health Impact (e.g., use behavior, health risk), Tobacco Product Perception and Intention Studies

k. Study Report(s) - examples of documents include:

- Study protocol
- Statistical analysis plan
- Study report
- Statistical software programming code
- Study instruments (e.g. surveys/questionnaires)
- Informed consent form
- Case Report Forms (as appropriate)

  In general Case Report Forms (CRFs) from clinical studies are not needed for filing a PMTA. However, FDA will require for filing the CFRs from clinical studies that have been made to show the health risks of the PMTA product and whether such product presents less risk than other tobacco products where the CRF: 1) relates to participant deaths, other serious and unexpected adverse experiences, or participant discontinuation (including withdrawals) AND 2) where the study participant was exposed to the tobacco product(s) which is/are the subject of the PMTA(s) or to a similar/related product that the applicant is using to show that the PMTA product meets the standard for marketing authorization under section 910. Additional information may be requested on a case-by-case basis during FDA review. FDA expects all CRFs would be available for review during Agency inspections of clinical and/or nonclinical study sites.

- Analyzable Data sets

  In general raw data such as raw chromatograms/spectra/mass spectra arising from analytical chemistry testing and raw (meaning no integration of the data) output from high-throughput (e.g., genomic) studies are not needed for filing a PMTA. Line data/analyzable datasets that are representative chromatograms/spectra/mass spectra that demonstrate the adequacy of separations/specificity, standard solution, and sample solutions should be included. The line data/analyzable data sets may be used to replicate findings or conduct alternative analyses of the underlying data. Additional information may be requested on a case-by-case basis during FDA review. FDA expects all raw data would be available for review during Agency inspection of clinical and/or nonclinical study sites.

- Other

Section V - Manufacturing/Packaging Sites Relating to a Submission

a. Provide the name of the Manufacturing/Packaging site (required by 21 CFR § 1114.7(j))
b. Select the appropriate box about company/institution manufacturing/packaging site
c. Provide Facility Establishment Identifier (FEI) Number (if applicable) (required by 21 CFR § 1114.7(j))
d. Provide D&B DUNS Number of Headquarters (if applicable)
e. Provide division name (required by 21 CFR § 1114.7(j))
f. Provide contact information (required by 21 CFR § 1114.7(j))
g. Provide information about the inspection readiness of the Manufacturing/Packaging facility
h. Provide information about additional sites as described in the submittal form, as applicable

Section VI - Statements of Compliance with the Federal Food, Drug and Cosmetic (FD&C) Act

Provide information for how the application meets the requirements and addresses the question(s) in each of the statements according to the Federal Food, Drug and Cosmetic (FD&C) Act as required by 21 CFR § 1114.7(c)(10) and (11).

Other Information

Identify and provide information for any additional information not captured in the PMTA submittal form that is pertinent to your application

We remind you that all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter.

We are unable to accept regulatory submissions by electronic mail.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 45 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff

For PRA questions:
PRAStaff@fda.hhs.gov

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