DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Premarket Tobacco Product Application (PMTA) Submission

Form Approved: OMB No. 0910-0879
Expiration Date: 12/31/2025
(See page 29 for PRA Statement)

Marketing without a Marketing Granted Order (MGO) is illegal and may be subject to enforcement.
Please carefully read the instructions located in the Appendix before completing this form.

SECTION I – APPLICANT IDENTIFICATION

Part A: Applicant Information[1]

Complete for either an organization or an individual, NOT both. Organization applicants should complete fields 1–20 only. Individual applicants should complete fields 21–36 only.

If applicant is an organization, complete Part A fields 1–20 and proceed to Part B.

1. Organization Name	2. Other Organization Names (if applicable)
3. Organization Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number	4. Organization Headquarters' D&B DUNS® Number

5. Submit Date *(mm/dd/yyyy)*	6. Street Address Line 1	7. Street Address Line 2 (Apt., Suite, Bldg., #)

8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

Point of Contact for Organization

12. First Name	13. Middle Initial	14. Last Name

15. Generational Suffix	16. Professional Suffix	17. Position Title

18. Phone Number	19. Fax Number	20. Email Address

If applicant is an individual, complete Part A fields 21–36 and proceed to Part B.

21. First Name	22. Middle Initial	23. Last Name	24. Submit Date *(mm/dd/yyyy)*

25. Generational Suffix	26. Professional Suffix	27. Position Title

28. Street Address Line 1	29. Street Address Line 2 (Apt., Suite, Bldg., #)

30. City	31. State, Province, or Territory	32. Country	33. ZIP or Postal Code

34. Phone Number	35. Fax Number	36. Email Address

Part B: Authorized Representative[1] or U.S. Agent Information[1]

☐ 1. Select if authorized representative or U.S. agent is the same as the applicant identified in Part A. If the same, skip Part B fields 2–18 and proceed to Part C.

2. Identify the authorized representative OR a U.S. agent (select one)

☐ **Authorized representative** (responsible official authorized to represent the domestic applicant)

OR

☐ **U.S. agent** (responsible official who either resides or maintains a place of business in the U.S. who is authorized to represent the foreign applicant)

Contact Information for the Authorized Representative or U.S. Agent

3. First Name	4. Middle Initial	5. Last Name	
6. Generational Suffix	7. Professional Suffix	8. Position Title	
9. Organization Name	10. Street Address Line 1	11. Street Address Line 2 (Apt., Suite, Bldg., #)	
12. City	13. State, Province, or Territory	14. Country	15. ZIP or Postal Code
16. Phone Number	17. Fax Number	18. Email Address	

Part C: Alternate Point of Contact Information (Optional)

Use the Continuation Page button below to list additional alternate points of contact.

1. Select alternate:

☐ Applicant ☐ Authorized representative ☐ U.S. agent ☐ Other

2. First Name	3. Middle Initial	4. Last Name	
5. Generational Suffix	6. Professional Suffix	7. Position Title	
8. Organization Name	9. Street Address Line 1	10. Street Address Line 2 (Apt., Suite, Bldg., #)	
11. City	12. State, Province, or Territory	13. Country	14. ZIP or Postal Code
15. Phone Number	16. Fax Number	17. Email Address	

[1] Required content and format as per §1114.7 (Standard PMTA), 1114.15 (Supplemental PMTA), and 1114.17 (Resubmission).

Continuation Page for Part C

Part D: Manufacturer Information[1]

☐ 1. Select here if manufacturer is the same as applicant identified in Part A. If the same, skip Part D fields 2–20 and proceed to Part E.

2. Organization Name	3. Organization Headquarters' FDA-assigned FEI Number (if applicable)	4. Organization Headquarters' D&B DUNS® Number (if applicable)

☐ 5. Select here if manufacturer address is the same as applicant address provided in Part A; if the same, skip fields 6–11 and proceed to field 12.

6. Street Address Line 1	7. Street Address Line 2 (Apt., Suite, Bldg., #)

8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

Point of Contact for Manufacturer

12. First Name	13. Middle Initial	14. Last Name	15. Generational Suffix	16. Professional Suffix

17. Position Title	18. Phone Number	19. Fax Number	20. Email Address

Part E: Manufacturer/Packaging/Sterilization Sites Information

Use the Continuation Page button below for each additional site.

1. Select type of site:

☐ Manufacturer ☐ Contract manufacturer ☐ Repacker/Relabeler

2. Organization Name	3. Organization Headquarters' FDA-Assigned FEI Number (if applicable)	4. Organization Headquarters' D&B DUNS® Number (if applicable)

5. Division Name (if applicable)	6. Is the manufacturing/packaging/sterilization site ready for inspection? ☐ Yes ☐ No

7. Street Address Line 1	8. Street Address Line 2 (Apt., Suite, Bldg., #)

9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

Point of Contact Information for Manufacturing/Packaging/Sterilization Sites

13. First Name	14. Middle Initial	15. Last Name	16. Generational Suffix	17. Professional Suffix

18. Position Title	19. Phone Number	20. Fax Number	21. Email Address

Continuation Page for Part E

SECTION II – NEW TOBACCO PRODUCT INFORMATION[1]

Use required Form FDA 4057b – Premarket Tobacco Product Application Grouping Product Submission Spreadsheet to provide new product information. The form is available on the FDA website.

SECTION III – SUBMISSION INFORMATION

Part A: General Submission Information

1. Identify submission type (select one):[1]

☐ Standard PMTA ☐ Resubmission ☐ Supplemental PMTA

2. For products that were previously commercially marketed in the United States, provide the product names and corresponding marketing date(s):[1]

Part B: Cross-Reference Information (Optional)

Complete one row per cross-reference submission. Use the Continuation Page button below to list additional cross-references.

1. Cross-Reference STN	2. Is the content relevant to all products within this submission?	3. Information and sections to be referenced (e.g., all sections, sections I–III)
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	

Continuation Page for Part B

Part C: Referenced Tobacco Product Master File(s) (TPMF) (Optional)

Complete fields 1–5 for each TPMF cross-reference. Use the Continuation Page button below to list additional TPMFs.

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

Continuation Page for Part C

Part D: Formal Meetings Held With FDA Pertaining to the New Product(s) (Optional)

Indicate one meeting per row. As needed, enter the STN and meeting held date.
Use the Continuation Page button below to list additional meetings.

1. Submission STN	2. Meeting Held Date[1] *(mm/dd/yyyy)*	3. Is the meeting relevant to all products within this submission?
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):

Continuation Page for Part D

SECTION IV – APPLICATION CONTENTS

This application contains the following items (Select all that apply and indicate file name and location of application content.)

Part A: Administrative Content

1. ☐ Cover Letter
   Location: _____
2. ☐ Comprehensive Index[1] and Table of Contents[1]
   Location: _____
3. ☐ English[1] Translations for Non-English Information
   Location: _____
4. ☐ Request for FDA to refer PMTA to TPSAC[1]
   Location: _____

Part B: Labeling and Marketing Plans

1. ☐ Specimens of all Proposed Labelling[1]
   Location: _____
2. ☐ Description of Marketing Plans[1]
   Location: _____

Part C: Inspections

1. ☐ Location and Contact Information for Each Location Subject to Potential Inspection
   Location: _____

Part D: Scientific Content

1. ☐ General Information[1]
   Location: _____
2. ☐ Descriptive Information[1]
   Location: _____
3. ☐ Product Samples[2]
   Location: _____
4. ☐ Statement of Compliance with 21 CFR part 25[1]
   Location: _____
5. ☐ Summary[1]
   Location: _____
6. ☐ Product Formulation[1]
   Location: _____
7. ☐ Manufacturing[1]
   Location: _____
8. ☐ Literature Search[1]
   Location: _____
9. ☐ Organized References
   Location: _____
10. ☐ Health Risk Investigations[1]
    Location: _____
11. ☐ Study Reports[1]
    Location: _____

[2] 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.

SECTION V – STATEMENTS OF COMPLIANCE WITH THE FEDERAL FOOD, DRUG AND COSMETIC (FD&C) ACT

1. Provide a brief description of how the PMTA satisfies content requirements of section 910(b)(1) of the FD&C Act in the space below:

2. Provide 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 increased or decreased likelihood that existing users of tobacco products will stop using such products; and
    - The increased or decreased likelihood that those who do not use tobacco products will start using such products.

SECTION VI – CERTIFICATION STATEMENTS

Applications 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:

i. Certification Statement for Standard PMTAs
ii. Modified Tobacco Product Certification for Supplemental PMTAs
iii. Same Product Certification for Resubmissions
iv. Different Product Certification for Resubmissions
v. Financial Interest and Arrangements of Clinical Investigators Certification Statement

For the following section, insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A, the individual new tobacco product(s), and the name of the previously submitted PMTA product(s). Complete the information for all applications. If you choose to print and wet sign the certification statements, upload them as a separate document from 4057 to maintain the dynamic fields in Adobe and ensure all content is available for FDA to process, read, review, and archive.

i. Certification Statement for Standard PMTAs:

I, (insert 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.

1. Signature and Date *(mm/dd/yyyy)*

ii. Modified Tobacco Product Certification for Supplemental PMTAs

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

1. Signature and Date *(mm/dd/yyyy)*

iii. Same Tobacco Product Certification for Resubmission

I, (insert 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.

1. Signature and Date *(mm/dd/yyyy)*

iv. 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.

1. Signature and Date (mm/dd/yyyy)

v. 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).

1. Signature and Date *(mm/dd/yyyy)*

SECTION VII – APPENDICES

CONTINUATION PAGES

Appendix A: Alternate Point of Contact Information

Submit a single Form FDA 4057 including all continuation additional page information. For Continuation Page entries requiring extra space to provide additional information, use the sections provided below. Fill out as many additional sections as needed, completing all fields within each section.

SECTION I, Part C: Alternate Point of Contact Information (Optional)

1. Select alternate:

☐ Applicant ☐ Authorized representative ☐ U.S. agent ☐ Other

2. First Name	3. Middle Initial	4. Last Name
5. Generational Suffix	6. Professional Suffix	7. Position Title
8. Organization Name	9. Street Address Line 1	10. Street Address Line 2 (Apt., Suite, Bldg., #)
11. City	12. State, Province, or Territory	13. Country / 14. ZIP or Postal Code
15. Phone Number	16. Fax Number	17. Email Address

SECTION I, Part C: Alternate Point of Contact Information (Optional)

1. Select alternate:

☐ Applicant ☐ Authorized representative ☐ U.S. agent ☐ Other

2. First Name	3. Middle Initial	4. Last Name
5. Generational Suffix	6. Professional Suffix	7. Position Title
8. Organization Name	9. Street Address Line 1	10. Street Address Line 2 (Apt., Suite, Bldg., #)
11. City	12. State, Province, or Territory	13. Country / 14. ZIP or Postal Code
15. Phone Number	16. Fax Number	17. Email Address

Appendix B: Manufacturer Information

Submit a single Form FDA 4057 including all continuation additional page information. For Continuation Page entries requiring extra space to provide additional information, use the sections provided below. Fill out as many additional sections as needed, completing all fields within each section.

SECTION I, Part E: Manufacturer/Packaging/Sterilization Sites Information

1. Select type of site: ☐ Manufacturer ☐ Contract manufacturer ☐ Repacker/Relabeler

2. Organization Name	3. Organization Headquarters' FDA-Assigned FEI Number (if applicable)	4. Organization Headquarters' D&B DUNS® Number (if applicable)

5. Division Name (if applicable)	6. Is the manufacturing/packaging/sterilization site ready for inspection? ☐ Yes ☐ No

7. Street Address Line 1	8. Street Address Line 2 (Apt., Suite, Bldg., #)

9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

Point of Contact Information for Manufacturing/Packaging/Sterilization Sites

13. First Name	14. Middle Initial	15. Last Name	16. Generational Suffix	17. Professional Suffix

18. Position Title	19. Phone Number	20. Fax Number	21. Email Address

SECTION I, Part E: Manufacturer/Packaging/Sterilization Sites Information

1. Select type of site: ☐ Manufacturer ☐ Contract manufacturer ☐ Repacker/Relabeler

2. Organization Name	3. Organization Headquarters' FDA-Assigned FEI Number (if applicable)	4. Organization Headquarters' D&B DUNS® Number (if applicable)

5. Division Name (if applicable)	6. Is the manufacturing/packaging/sterilization site ready for inspection? ☐ Yes ☐ No

7. Street Address Line 1	8. Street Address Line 2 (Apt., Suite, Bldg., #)

9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

Point of Contact Information for Manufacturing/Packaging/Sterilization Sites

13. First Name	14. Middle Initial	15. Last Name	16. Generational Suffix	17. Professional Suffix

18. Position Title	19. Phone Number	20. Fax Number	21. Email Address

Appendix C: Cross-Reference Information

Submit a single Form FDA 4057 including all continuation additional page information. For Continuation Page entries requiring extra space to provide additional information, use the sections provided below. Fill out as many additional sections as needed, completing all fields within each section.

1. Cross-Reference STN	2. Is the content relevant to all products within this submission?	3. Information and sections to be referenced (e.g., all sections, sections I–III)
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	
	☐ Yes ☐ No (list applicable product name[s]):	

Appendix D: Referenced Tobacco Product Master File(s) (TPMF)

Submit a single Form FDA 4057 including all continuation additional page information. For Continuation Page entries requiring extra space to provide additional information, use the sections provided below. Fill out as many additional sections as needed, completing all fields within each section.

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

1. TPMF Owner	2. TPMF STN (assigned by FDA)
3. Is the content applicable to all products within this submission?	☐ Yes ☐ No (list applicable product name[s]):
4. Information and sections to be referenced (e.g., all sections, sections I–III)	
5. Right of reference included[1]	☐ Yes ☐ No

Appendix E: Formal Meetings Held With FDA Pertaining to the New Product(s)

Submit a single Form FDA 4057 including all continuation additional page information. For Continuation Page entries requiring extra space to provide additional information, use the sections provided below. Fill out as many additional sections as needed, completing all fields within each section.

1. Submission STN	2. Meeting Held Date[1] *(mm/dd/yyyy)*	3. Is the meeting relevant to all products within this submission?
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):
		☐ Yes ☐ No (list applicable product name[s]):

APPENDIX F: 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).

Form FDA 4057 - Premarket Tobacco Product Application (PMTA) Submission is a required form for applicants to use when submitting a PMTA to FDA. The numbered items in the below instructions correspond to those provided on the form. Prior to submitting to FDA, ensure all information entered in each field is readable after saving. For more information on what to include in a PMTA submission, see 21 CFR § 1114.7.

SECTION I – APPLICANT IDENTIFICATION

Section I should include information regarding the identity of the applicant, including the following parts:

Part A: Applicant Information

Part B: Authorized Representative or U.S. Agent Information

Part C: Alternate Point of Contact Information

Part D: Manufacturer Information

Part E: Manufacturer/Packing/Sterilization Sites Information

Part A: Applicant Information

Part A should include information regarding the applicant for the submission. An applicant may be any person that submits a PMTA who seeks a marketing authorization for a new tobacco product. Part A should be completed for either an organization applicant or an individual applicant, NOT both.

Note: For Part A, organization applicants should complete items 1–20 only. Individual applicants should complete fields 21–36 only.

If applicant is an organization, complete Part A fields 1–20 and proceed to Part B.

For these fields, provide the following information for the organization:

I.A.1. The organization name is the party who takes responsibility for and initiates the submission of a premarket tobacco product application to FDA. The legal name of the organization may be an individual or company name (private or otherwise) and should match the applicant's Dun & Bradstreet Data Universal Numbering System (D&B DUNS®) number.

I.A.2. All other names the applicant operates under (e.g., any "Doing Business As" [D.B.A.]), if applicable.

I.A.3. The organization headquarters' FDA-assigned Facility Establishment Identifier (FEI) number, if applicable.

Note: To obtain or retrieve an FEI number, applicants can use the FEI Search Portal at https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login, and/or contact FEI Search Portal support at feiportal@fda.hhs.gov for any FEI number-related questions.

I.A.4. The organization headquarters' D&B DUNS number, if applicable.

Note: To obtain or retrieve a DUNS number, applicants can contact Dun and Bradstreet directly by phone at +1 -866-705-5711 or through their website at https://www.dnb.com/duns/get-a-duns.html.

I.A.5. The date you are formally submitting the application to FDA (e.g., submitting via the CTP Portal, the FDA Electronic Submissions Gateway [ESG], or handed to courier).

I.A.6. The street address for the organization (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.

I.A.7. Additional street address information for the organization location (including apartment, suite, or building number) that you were not able to include in I.A.6.

I.A.8. The city of the organization location.

I.A.9. The state, province, or territory of the organization location.

I.A.10. The country of the organization location.

I.A.11. The ZIP or postal code of the organization location.

Point of Contact for Organization (only complete if applicant is an organization)

- **I.A.12.** The first name of the organization point of contact.
- **I.A.13.** The middle initial of the organization point of contact**,** if applicable.
- **I.A.14.** The last name of the organization point of contact.
- **I.A.15.** The generational suffix (e.g., Jr., III) for the of the organization point of contact, if applicable.
- **I.A.16.** The professional suffix (e.g., M.D., Ph.D.) of the organization point of contact, if applicable.
- **I.A.17.** The professional position title of the organization point of contact.
- **I.A.18.** The phone number of the organization point of contact (include country code, if applicable and area code).
- **I.A.19.** The fax number of the organization point of contact, if applicable (include country code, if applicable and area code).
- **I.A.20.** The email address of the organization point of contact.

If applicant is an individual, complete Part A fields 21–36 and proceed to Part B

For these fields, provide the following information for the individual applicant:

- **I.A.21.** The first name of the individual applicant.
- **I.A.22.** The middle initial of the individual applicant, if applicable.
- **I.A.23.** The last name of the individual applicant.
- **I.A.24.** The submit date, or date you are formally sending the submission to FDA (e.g., submitting via the CTP Portal, or the FDA Electronic Submissions Gateway [ESG]).
- **I.A.25.** The generational suffix (e.g., Jr., III) for the individual applicant, if applicable.
- **I.A.26.** The professional suffix (e.g., M.D., Ph.D.) for the individual applicant, if applicable.
- **I.A.27.** The professional position title of the individual applicant.
- **I.A.28.** The street address for the individual applicant (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.
- **I.A.29.** Additional street address information for the individual applicant (including apartment, suite, or building number) that you were not able to include in I.A.28.
- **I.A.30.** The city of the individual applicant.
- **I.A.31.** The state, province, or territory of the individual applicant.
- **I.A.32.** The country of the individual applicant.
- **I.A.33.** The ZIP or postal code of the individual applicant.
- **I.A.34.** The phone number of the individual applicant (include country code, if applicable and area code).
- **I.A.35.** The fax number of the individual applicant, if applicable (include country code, if applicable and area code).
- **I.A.36.** The email address of the individual applicant.

Part B: Authorized Representative or U.S. Agent Information

Part B should include information for either an authorized representative OR U.S. agent (for a foreign applicant).
For these fields, provide the following information for the authorized representative or U.S. agent:

- **I.B.1.** Select the checkbox if the authorized representative/U.S. agent and applicant information is the same as the applicant identified in Part A . If the same, skip Part B fields 2–18 and proceed to Part C.
- **I.B.2.** Select only one checkbox to indicate whether you are completing Part B for either an authorized representative or a U.S. agent.
- **I.B.3.** The first name of the authorized representative or the U.S. agent.
- **I.B.4.** The middle initial of the authorized representative or the U.S. agent, if applicable.
- **I.B.5.** The last name of the authorized representative or the U.S. agent.
- **I.B.6.** The generational suffix (e.g., Jr., III) of the authorized representative or the U.S. agent, if applicable.
- **I.B.7.** The professional suffix (e.g., M.D., Ph.D.) of the authorized representative or the U.S. agent, if applicable.
- **I.B.8.** The professional position title of the authorized representative or the U.S. agent.
- **I.B.9.** The legal name of the organization that the authorized representative or U.S. agent is associated with, if applicable.

I.B.10. The street address for the authorized representative or the U.S. agent (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.

I.B.11. Additional street address information for the authorized representative or the U.S. agent (including apartment, suite, or building number) that you were not able to include in I.B.10.

I.B.12. The city of the authorized representative or the U.S. agent.

I.B.13. The state, province, or territory of the authorized representative or the U.S. agent.

I.B.14. The country of the authorized representative or the U.S. agent.

I.B.15. The ZIP or postal code of the authorized representative or the U.S. agent.

I.B.16. The phone number of the authorized representative or the U.S. agent (include country code, if applicable and area code).

I.B.17. The fax number of the authorized representative or the U.S. agent, if applicable (include country code, if applicable and area code).

I.B.18. The email address of the authorized representative or the U.S. agent.

Part C: Alternate Point of Contact Information (Optional)

Part C is an optional space for information for individuals not previously listed in Section I Parts A and/or B. Use the Continuation Page button within the form for additional alternate points of contact, as needed.

For these fields, provide the following information for the alternate point of contact:

I.C.1. Indicate whether the alternate point of contact is one of the following:

- Applicant
- Authorized representative*
- U.S. agent*
- Other

Note: Only contacts listed as the authorized representative and/or U.S. agent are authorized to act on behalf of the applicant for the submission.

I.C.2. The first name of the individual.

I.C.3. The middle initial of the individual.

I.C.4. The last name of the individual.

I.C.5. The generational suffix (e.g., Jr., III) for the individual, if applicable.

I.C.6. The professional suffix (e.g., M.D., Ph.D.) for the individual, if applicable.

I.C.7. The professional position title of the individual.

I.C.8. The legal name of the organization of the individual, if applicable.

I.C.9. The street address for the individual (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.

I.C.10. Additional street address information for the individual (including apartment, suite, or building number) that you were not able to include in I.C.9.

I.C.11. The city of the individual.

I.C.12. The state, province, or territory of the individual.

I.C.13. The country of the individual.

I.C.14. The ZIP or postal code of the individual.

I.C.15. The phone number of the individual (include country code, if applicable, and area code).

I.C.16. The fax number of the individual (include country code, if applicable, and area code).

I.C.17. The email address of the individual.

Part D: Manufacturing Information

Only complete this section if the manufacturer information is different from the applicant. If this information is the same as the applicant, check the checkbox in I.D.1, skip Part D fields 2–20 and proceed to Part E.

I.D.1. Select the checkbox if the manufacturer and applicant information is the same. If the same, skip Part D fields 2–20.

I.D.2. The legal name of the manufacturer as it appears in the manufacturer's Dun & Bradstreet Data Universal Numbering System D-U-N-S® (D&B DUNS®) number.

I.D.3. The manufacturer headquarters' FDA-assigned Facility Establishment Identifier (FEI) number, if applicable.
Note: To obtain or retrieve an FEI number, applicants can use the FEI Search Portal at https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login, and/or contact FEI Search Portal support at feiportal@fda.hhs.gov for any FEI number-related questions.

I.D.4. The manufacturer headquarters' D&B DUNS number, if applicable.
Note: To obtain or retrieve a DUNS number, applicants can contact Dun and Bradstreet directly by phone at 1.866.705.5711 or through their website at https://www.dnb.com/duns/get-a-duns.html.

I.D.5. Select the checkbox if the manufacturer address is the same as the applicant address, skip Part D fields 6–11 and proceed to Part D field 12.

I.D.6. The street address for the manufacturer (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.

I.D.7. Additional street address information for the manufacturer location (including apartment, suite, or building number) that you were not able to include in I.D.6.

I.D.8. The city where the manufacturer is located.

I.D.9. The state, province, or territory where the manufacturer is located.

I.D.10. The country where the manufacturer is located.

I.D.11. The ZIP or postal code where the manufacturer is located.

Point of Contact for Manufacturer

I.D.12. The first name of the manufacturer point of contact.

I.D.13. The middle initial of the manufacturer point of contact**,** if applicable.

I.D.14. The last name of the manufacturer point of contact.

I.D.15. The generational suffix (e.g., Jr., III) for the of the manufacturer point of contact, if applicable.

I.D.16. The professional suffix (e.g., M.D., Ph.D.) of the manufacturer point of contact, if applicable.

I.D.17. The professional position title of the manufacturer point of contact.

I.D.18. The phone number of the manufacturer point of contact (include country code if applicable and area code).

I.D.19. The fax number of the manufacturer point of contact, if applicable (include country code if applicable and area code).

I.D.20. The email address of the manufacturer point of contact.

Part E: Manufacturer/Packing/Sterilization Sites Information

Part E is an optional space for information for additional manufacturing sites. Use the Continuation Page button within the form for additional sites, as needed.

For these fields, provide the following information for the manufacturing/packing/sterilization sites:

I.E.1. Select the field for the type of site.

I.E.2. The organization name for the manufacturing/packing/sterilization site (required by 21 CFR § 1114.7(j)).

I.E.3. The manufacturer headquarters' FDA-assigned Facility Establishment Identifier (FEI) number, if applicable (required by 21 CFR § 1114.7(j)).

I.E.4. The manufacturer headquarters' D&B DUNS number if applicable.
Note: To obtain or retrieve a DUNS number, applicants can contact Dun and Bradstreet directly by phone at 1.866.705.5711, at their website https://www.dnb.com/duns/get-a-duns.html.

I.E.5. The manufacturing/packing/sterilization sites division name, if applicable (required by 21 CFR § 1114.7(j)).

I.E.6. The manufacturing/packing/sterilization site is ready for inspection by checking “Yes” or “No”.

I.E.7. The street address for the manufacturer/packing/sterilization site (include street number, street name, and street type, and suffix direction, etc.) (required by 21 CFR § 1114.7(j)). The street address cannot be a P.O. Box.

I.E.8. Additional street address information (including apartment, suite, or building number) that you were not able to include in I.E.7 (required by 21 CFR § 1114.7(j)).

I.E.9. The city where the manufacturer/packing/sterilization site is located (required by 21 CFR § 1114.7(j)).

I.E.10. The state, province, or territory where the manufacturer/packing/sterilization site is located.

I.E.11. The country where the manufacturer/packing/sterilization site is located (required by 21 CFR § 1114.7(j)).

I.E.12. The ZIP or postal code where the manufacturer/packing/sterilization site is located (required by 21 CFR § 1114.7(j)).

Point of Contact Information for Manufacturing/Packaging/Sterilization Sites

For these fields, provide the following information for the manufacturer/packing/sterilization point of contact.

I.E.13. The first name of the manufacturer/packing/sterilization point of contact (required by 21 CFR § 1114.7(j)).

I.E.14. The middle initial of the manufacturer/packing/sterilization point of contact, if applicable (required by 21 CFR § 1114.7(j)).

I.E.15. The last name of the manufacturer/packing/sterilization point of contact (required by 21 CFR § 1114.7(j)).

I.E.16. The generational suffix (e.g., Jr., III) of the manufacturer/packing/sterilization point of contact, if applicable.

I.E.17. The professional suffix (e.g., M.D., Ph.D.) of the manufacturer/packing/sterilization point of contact, if applicable.

I.E.18. The position title for the of the manufacturer/packing/sterilization point of contact, if applicable (required by 21 CFR § 1114.7(j)).

I.E.19. The phone number of the manufacturer/packing/sterilization point of contact (include country code if applicable and area code) (required by 21 CFR § 1114.7(j)).

I.E.20. The fax number of the manufacturer/packing/sterilization point of contact, if applicable (include country code if applicable and area code) (required by 21 CFR § 1114.7(j)).

I.E.21. The email address of the manufacturer/packing/sterilization point of contact (required by 21 CFR § 1114.7(j)).

SECTION II – NEW TOBACCO PRODUCT INFORMATION

Utilize form FDA-4057b Premarket Tobacco Product Application Grouping Product Submission Spreadsheet available on the FDA website to provide new tobacco product(s) information.

SECTION III – SUBMISSION INFORMATION

Section III should include submission information, including the following parts:

Part A: Submission Type

Part B: Cross-Referenced Information

Part C: Referenced Tobacco Product Master File(s) (TPMF)

Part D: Formal Meetings Held With FDA Pertaining to this Tobacco Product

Part A: General Submission Information

III.A.1. Select the appropriate PMTA submission type: Standard, Resubmission, or Supplemental (as defined below).

- A **standard PMTA** is a submission from an applicant seeking a marketing granted order to introduce a new tobacco product into interstate commerce. 21 CFR § 1114.7
- A **resubmission PMTA** is submitted 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. 21 CFR § 1114.17
- 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 previous marketing granted order. 21 CFR § 1114.15.15

III.A.2. If the new products were previously commercially marketed in the United States, list the product name and provide the date(s) during which the product(s) were previously marketed.

Part B: Cross-Reference Information (Optional)

Complete Part B if the application includes one or more cross-reference(s) to another PMTA or MRTPA 21 CFR § 1114.7(b), § 1114.15(b), or § 1114.17(b). Supplemental PMTAs and resubmissions may cross-reference content in standard PMTAs. Standard PMTAs should not cross-reference another Standard PMTA or other pending applications with the exception of a pending MRTPA for the same tobacco product. Within the table, utilize a single row for each cross-reference. Use the Continuation Page button within the form to provide additional cross-references, as needed.

III.B.1. In column 1, provide the FDA submission tracking number (STN) for the cross-reference submission.

III.B.2. In column 2, identify if the cross reference provided in column 1 is for all products in the submission. If the cross reference is only for some of the new products in the submission select “no” and list the name of the product(s) that reference the cross reference.

III.B.3. In column 3, identify what information in the cross-reference submission you are seeking to reference for your new submission. For example, if you have the specific file name, document name and page number, please list them.

Part C: Referenced Tobacco Product Master File(s) (TPMF) (Optional)

Complete Part C if the application includes a Tobacco Product Master File (TPMF) 21 CFR § 1114.7 (b)(2). Boxes 1–5 should be provided for each TPMF. Use the Continuation Page button within the form for additional TPMFs, as needed.

III.C.1. In field 1, identify the TPMF owner.

III.C.2. In field 2, provide FDA the submission tracking number (STN) of the TPMF. When a TPMF is established by FDA, the TPMF STN is provided to the owner and can be referenced by the TPMF owner and/or an authorized party. If the TPMF is not established at time of application submission, insert “N/A”.

III.C.3. In field 3, identify if the TPMF is applicable to all products in the submission. If the TPMF is only for some of the new products in the submission, select “no” and list the name of the product(s) that reference the TPMF.

III.C.4. In field 4, identify what information in the TPMF you are seeking to reference for the new submission(s).

III.C.5. In field 5, indicate if the right of reference is included in the submission. The TPMF owner may authorize another party to reference information contained within a TPMF through a right of reference such as a letter of authorization (LOA).

Part D: Formal Meetings Held With FDA Pertaining to the New Product(s) (Optional)

Complete Part D if FDA and the applicant held one or more meetings related to the new product(s). This can include meetings for study design, earlier versions of the product, etc. Within the table, utilize a single row for each meeting. Use the Continuation Page button within the form to list additional meetings, as needed.

III.D.1. In column 1, provide the FDA submission tracking number (STN) for the industry meeting.

III.D.2. In column 2, identify the date of the meeting between FDA and the applicant.

III.D.3. In column 3, identify if the meeting topic was for all products in the submission. If the meeting relates only to some of the new products in the submission, select "no" and list the name(s) of the product(s) to which the meeting pertained.

SECTION IV – APPLICATION CONTENTS

Section IV is intended to help applicants organize their submission per 21 CFR § 1114.7. For each item included in your submission, select the corresponding checkbox in the list and provide the location of the document. (For example, the file name, document name and page number). Select all that apply.

Part A: Administrative Content

IV.A.1. Cover Letter

IV.A.2. Comprehensive Index (i.e., a listing of files and data associated with those files) (21 CFR § 1114.7(b)(1)) and Table of Contents (21 CFR § 1114.7(b)(1).

IV.A.3. Written in English or accompanied by an English translation for non-English information (21 CFR § 1114.7(b)(1)). For any document that contains content that is not in English, translation is required. If all contents of the application are in English, leave the box blank. If you are providing translations for non-English information, select the checkbox.

IV.A.4. Request for FDA to Refer PMTA to Tobacco Product Scientific Advisory Committee is optional. Select the checkbox if you are requesting a referral to TPSAC (21 CFR § 1114.7(c)(5)).

Part B: Labeling and Marketing Plans

IV.B.1. Specimens of all proposed labeling (21 CFR § 1114.7(f)(1)).

IV.B.2. Marketing plans (21 CFR § 1114.7(f)(2)).

Part C: Inspections

IV.C.1. Location and contact information for each location subject to potential inspection (21 CFR § 1114.7(k)(3)(vii)). Inspections may be conducted for manufacturing, clinical, or nonclinical sites.

Part D: Scientific Content

IV.D.1. General information (e.g., product name, product category, subcategory and product properties) (21 CFR § 1114.7(c)).

IV.D.2. Descriptive information (21 CFR § 1114.7(d)).

Part D: Scientific Content

IV.D.3. Product samples (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 21 CFR § 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. Pre-submission 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.

IV.D.4. Statement of compliance with 21 CFR part 25 (e.g., Environmental Assessment) (21 CFR § 1114.7(g)).

IV.D.5. Summary (21 CFR §1114.7(h)).

IV.D.6. Product formulation (e.g., components, ingredients, additives, properties, and principles of operations) (21 CFR § 1114.7(i)).

IV.D.7. Manufacturing (e.g., methods, facilities, controls) (21 CFR § 1114.7(j)).

IV.D.8. Literature search (21 CFR § 1114.7(k)(2)). A literature search 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, and (5) a bibliography of referenced publications.

IV.D.9. Organized references used to compile information in the submission.

IV.D.10. Health risk investigations (21 CFR § 1114.7(k)). Examples of health risk investigations include but are not limited to: Toxicological Risk Evaluation, Health Impact (e.g., use behavior, health risk), and Tobacco Product Perception and Intention Studies.

IV.D.11. 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 (CRFs):
  - In general, CRFs from clinical studies are not needed for filing a PMTA. However, FDA will require them for filing the CRFs 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.

SECTION V – STATEMENTS OF COMPLIANCE WITH THE FEDERAL FOOD, DRUG AND COSMETIC (FD&C) ACT

V.1. Provide information for how the application meets the requirements and addresses the question(s) in each of the statements according to the requirements section 910(b)(1) of the FD&C Act as required by 21 CFR § 1114.7(c)(10) and (11). Your descriptions should address:

- Full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products.
- Full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product.
- Full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product.
- An identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard.
- Specimens of the labeling proposed to be used for such tobacco product.
- Such other information relevant to the subject matter of the application as the Secretary may require.

V.2. Provide 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 increased or decreased likelihood that existing users of tobacco products will stop using such products.
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

SECTION VI – 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.

Provide the name of authorized representative who is signing the certification. Insert name of authorized representative as identified in Section I Part B or Part C.

Provide the name of the applicant being represented in the certification. Insert name of applicant as identified in Section I Part A.

The required Certification Statements (i.–v.) are based on the specific type of PMTA you are submitting, as follows:

i. **Certification statement for standard PMTAs** is appropriate when submitting a standard PMTA.

Insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A.

ii. **Modified tobacco product certification for supplemental PMTAs** is appropriate when submitting a supplemental PMTA.

Insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A, the individual new product(s) names(s), a description of each modification, and the name and STN of the previously submitted PMTA where appropriate in the statement. If submitting multiple products, it is recommended a separate certification is submitted for each product.

iii. **Same product certification for resubmissions** is appropriate when submitting a resubmission PMTA where the product is unchanged, and the applicant is addressing deficiencies outlined in the marketing denial order (MDO).

Insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A, the individual new product(s) names(s), and the STN of the previously submitted PMTA where appropriate in the statement.

iv. **Different product certification for resubmissions** is appropriate when submitting a resubmission PMTA where the product is a modification of the previously submitted PMTA that results from changes necessary to address the deficiencies outlined in the marketing denial order (MDO).

Insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A, the individual new product(s) names(s), the name and the STN of the previously submitted PMTA, and a description of each modification where appropriate in the statement. If submitting multiple products, it is recommended a separate certification is submitted for each product.

v. **Financial Interest and Arrangements of Clinical Investigators Certification Statement** is appropriate when submitting any type of PMTA and must be included if your application includes any type of study in support of this application. This certification covers all actions taken to ensure the reliability of the study.

Insert the name of the authorized representative as identified in Section I Part B or Part C, and the name of the organization being represented as identified in Section I Part A.

For each certification statement applicable, insert the signature of the authorized representative and the date the certification is signed.

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 1997.
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 35 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

OMB Statement: “An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”