DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TOBACCO SUBSTANTIAL EQUIVALENCE REPORT SUBMISSION

Form Approved: OMB No. 0910-0673
Expiration Date: 4/30/2028

Marketing a new tobacco product without a Substantially Equivalent Order is illegal and may be subject to enforcement.[1]
Please carefully read the instructions located in Appendix G before completing this form.

SECTION I – APPLICANT IDENTIFICATION

1. Identify whether the applicant is a manufacturer OR importer *(select one)*[2]:

☐ Manufacturer ☐ Importer

Part A: Applicant Information[2]

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 Name (if applicable)
3. Organization FDA-Assigned Facility Establishment Identifier (FEI) Number	4. Organization 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

[1] A tobacco product that was introduced or delivered for introduction into interstate commerce after February 15, 2007, and prior to March 22, 2011, and for which a Substantial Equivalence (SE) Report was submitted by March 22, 2011 (Provisional SE Reports), may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent.

[2] Required content and format as per 21 CFR 1107.18.

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[2] or U.S. Agent Information[2]

☐ 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

Continuation Page for Part C

Part D: Manufacturer Information[2]

Use the Continuation Page button below to list additional manufacturers.

New Product(s) Manufacturer

☐ 1. Select here if New Product Manufacturer is the same as applicant provided in Part A; if the same, skip fields 2–19 and proceed to Predicate Product(s) Manufacturer field 20.

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

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

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

Point of Contact for New Product(s) Manufacturer

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

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

Continuation Page for Part D

Predicate Product(s) Manufacturer

☐ 20. Select here if Predicate Product Manufacturer is the same as Applicant identified in Part A; skip Part D fields 21–39 and proceed to Part E.

☐ 21. Select here if Predicate Product Manufacturer is the same as New Product(s) Manufacturer identified in Part D 2–19; skip Part D fields 22–39 and proceed to Part E.

22. Organization Name	23. Organization FDA-Assigned FEI Number (if applicable)	24. Organization D&B DUNS® Number (if applicable)
25. Street Address Line 1	26. Street Address Line 2 *(Apt., Suite, Bldg., #)*	
27. City	28. State, Province, or Territory	29. Country	30. ZIP or Postal Code

Point of Contact for Predicate Product(s) Manufacturer

31. First Name	32. Middle Initial	33. Last Name	34. Generational Suffix	35. Professional Suffix
36. Position Title	37. Phone Number	38. Fax Number	39. Email Address	

Continuation Page for Part D

Part E: Manufacturer/Packaging/Storage/Control Facility Information (Optional)
Use the Continuation Page button below for each additional site.

1. Select type of site *(select one)*:

☐ Manufacturer ☐ Contract manufacturer ☐ Repacker/relabeler ☐ Other _____

2. Alternate manufacturing site for:

☐ New product(s) manufacturer ☐ Predicate product(s) manufacturer ☐ Both new and predicate product(s) manufacturer

3. Organization Name	4. Organization FDA-Assigned FEI Number (if applicable)	5. Organization D&B DUNS® Number (if applicable)
6. Division Name (if applicable)		
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 for Manufacturer/Packaging/Storage/Control Facility Information				
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 PRODUCT(S) INFORMATION[2]

Use required Form FDA 3965b – Tobacco Substantial Equivalence Report Unique Identifying Information for New Tobacco Product Spreadsheet to provide new and predicate product information. The form is available on the FDA website.

SECTION III – PREDICATE PRODUCT(S) ELIGIBILITY[2]

Part A: Predicate Product(s) Status

1. Select all statements below that apply to the predicate tobacco product(s). Complete all necessary information for each statement.

☐ **Previously Found SE**
–If selected, skip Part B.

☐ **PTP Determined**
–If selected, complete the i. Certification Statement of Affirmation in Section VI.

☐ **Claimed PTP**
–If selected, complete Part B and the i. Certification Statement of Affirmation in Section VI.

Part B: Evidence of Commercial Marketing as of February 15, 2007

1. Type of Evidence *(e.g., Invoice)*	2. Date of Evidence *(mm/dd/yyyy)*
3. Evidence Identifier *(e.g., Invoice Number)*	4. Commercial Information *(e.g., UPC Code, product description, item number)*
5. Predicate Product Name(s)	

Business Addresses Associated with Evidence of Commercial Marketing (optional)			
6. (Ship from) Street Address Line 1		7. (Ship from) Street Address Line 2 *(Apt., Suite, Bldg., #)*	
8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code
12. (Ship to) Street Address Line 1		13. (Ship to) Street Address Line 2 *(Apt., Suite, Bldg., #)*	
14. City	15. State, Province, or Territory	16. Country	17. ZIP or Postal Code

SECTION IV – SUBMISSION INFORMATION

Part A: General Submission Information

Applicants may bundle groups of SE Reports for their new product(s) in the same product category and subcategory where the proposed modifications are the same.

1. **Type of Application²** *Select only one.*

☐ Same Characteristics Reports ☐ Different Characteristics Reports

2. **Submission Summaries²** *As described in 21 CFR 1107.18(d), please summarize the submission below.*

3. **Proposed modification(s) to the tobacco product(s) (as compared to the predicate tobacco product[s])²**
Select all that apply.

☐ Tobacco Blend ☐ Design ☐ Materials

☐ Container Closure System ☐ Heating Source ☐ Product Quantity

☐ Composition ☐ Other *(Specify):*_____

☐ Ingredients *(Specify below):*

Part B: Cross-Referenced Information (Optional)

Complete one row per Cross-Referenced submission. Use the Continuation Page button below to list additional Cross-References.

1. Cross-Referenced 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–IV)
	☐ 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]):	

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 ☐ 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 ☐ 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 ☐ Yes ☐ No	

Continuation Page for Part C

Part D: Formal Meetings Held with FDA Pertaining to the New Product(s)[2] (If Applicable)

Indicate one meeting per row. As appropriate, enter the STN and meeting held date.

Use the Continuation Page button below to list additional meetings.

1. Submission STN	2. Meeting Held Date *(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 V – 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[2] and Table of Contents[2]
   Location: _____
3. ☐ Unique Identification of New Tobacco Product(s) and Predicate Tobacco Product(s) *(Form FDA 3965b - Tobacco Substantial Equivalence Report Unique Identifying Information for New Tobacco Product Spreadsheet)*[2]
   Location: _____
4. ☐ English Translations for Non-English Information[2]
   Location: _____

Part B: Product Information[2]

1. ☐ List of Ingredients
   Location: _____
2. ☐ Information on Manufacturing Process
   Location: _____
3. ☐ Statement of Compliance with Applicable Tobacco Product Standards
   Location: _____

Part C: Health and Research[2] *(Select only one)*

1. ☐ Health Information Summary
   Location: _____

   OR
2. ☐ Health Information Statement
   Location: _____

Part D: Comparisons[2]

(New vs. Predicate Tobacco Product)

1. ☐ Product Design
   Location: _____
2. ☐ Heating Source
   Location: _____
3. ☐ Composition
   - ☐ Materials
   - ☐ Ingredients, tobacco
   - ☐ Ingredients, non-tobacco

   Location: _____
4. ☐ Other features
   - ☐ HPHCs
   - ☐ Other *(specify:)* _____

   Location: _____
5. ☐ Stability
   Location: _____
6. ☐ Comparison to Original Predicate Tobacco Product(s) *(Select only if the predicate product was previously found SE)*
   Location: _____

Part E: Environmental Considerations[2] *(Select only one)*

1. ☐ Environmental Assessment
   Location: _____

   OR
2. ☐ Claim for Categorical Exclusion
   Location: _____

SECTION VI – CERTIFICATION STATEMENTS

The SE Report must contain the following certification, with the appropriate information inserted (as indicated by the parenthetical text), and be signed by an authorized representative of the applicant:

i. Certification Statement of Affirmation
ii. Certification Statement for SE Report
iii. Certification Statement for Same Characteristics SE Report
iv. Certification Statement regarding availability of health information

For the following section, insert the name of an authorized representative(s) or U.S. agent 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 predicate tobacco 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 Form FDA 3965 to maintain the dynamic fields in Adobe and ensure all content is available for FDA to process, read, review, and archive.

i. Certification Statement of Affirmation:

I, *(name of responsible official)* _____, confirm that the predicate tobacco product(s) listed below was/were commercially marketed (other than for test marketing) in the United States as of February 15, 2007.

1. Name of predicate tobacco product(s)

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

ii. Certification Statement for SE Report[2]:

I, *(name of responsible official)* _____, on behalf of *(name of applicant)* _____ hereby certify that *(name of applicant)* _____ will maintain all records to substantiate the accuracy of this SE Report for the period of time required in 21 CFR 1107.58 and ensure that such 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)*

iii. Certification Statement for Same Characteristics SE Report[2]:

I, *(name of responsible official)*_____, on behalf of *(name of company)* _____, certify that *(name of new tobacco product)* _____ has the following modification(s) as compared to *(name of predicate tobacco product)*_____ due to the following modification(s): *(describe modification(s), e.g., change in product quantity or change in container closure system*) _____.

Aside from these modifications, the characteristics of *(name of new tobacco product)* _____ and *(name of predicate tobacco product)* _____ are identical. I certify that *(name of company*) _____understands this means there is no other modification to the materials, ingredients, design features, heating source, or any other feature. I also certify that *(name of company)* _____will maintain records to support the comparison information in 21 CFR 1107.19 that substantiate the accuracy of this statement for the period of time required in 21 CFR 1107.58, and ensure that such records remain readily available to FDA upon request.

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

iv. Certification Statement Regarding Availability of Health Information[2]:

910(a)(4) Health Information Statement

I, *(name of responsible official)*_____, certify that, in my capacity as *(the position held in company by person required to submit the SE Report, preferably the responsible official of the applicant)* _____ of *(name of company)*_____, I will make available, upon request, the information identified in 21 CFR 1107.18(j)(3) within 30 calendar days of a request.

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

SECTION VII – APPENDICES

CONTINUATION PAGES

Appendix A: Alternate Point of Contact Information

Submit a single Form FDA 3965 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 3965 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 D: Manufacturer Information

New Product(s) Manufacturer

☐ 1. Select here if New Product Manufacturer is the same as applicant provided in Part A; if the same, skip fields 2–19 and proceed to Predicate Product(s) Manufacturer field 20.

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

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

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

Point of Contact for New Product(s) Manufacturer

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

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

Predicate Product(s) Manufacturer

☐ 20. Select here if Predicate Product Manufacturer is the same as Applicant identified in Part A; skip Part D fields 21–39 and proceed to Part E.

☐ 21. Select here if Predicate Product Manufacturer is the same as New Product(s) Manufacturer identified in Part D 2–19; skip Part D fields 22–39 and proceed to Part E.

22. Organization Name	23. Organization FDA-Assigned FEI Number (if applicable)	24. Organization D&B DUNS® Number (if applicable)

25. Street Address Line 1	26. Street Address Line 2 *(Apt., Suite, Bldg., #)*

27. City	28. State, Province, or Territory	29. Country	30. ZIP or Postal Code

Point of Contact for Predicate Product(s) Manufacturer

31. First Name	32. Middle Initial	33. Last Name	34. Generational Suffix	35. Professional Suffix

36. Position Title	37. Phone Number	38. Fax Number	39. Email Address

SECTION I, Part D: Manufacturer Information

New Product(s) Manufacturer

☐ 1. Select here if New Product Manufacturer is the same as applicant provided in Part A; if the same, skip fields 2–19 and proceed to Predicate Product(s) Manufacturer field 20.

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

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

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

Point of Contact for New Product(s) Manufacturer

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

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

Predicate Product(s) Manufacturer

☐ 20. Select here if Predicate Product Manufacturer is the same as Applicant identified in Part A; skip Part D fields 21–39 and proceed to Part E.

☐ 21. Select here if Predicate Product Manufacturer is the same as New Product(s) Manufacturer identified in Part D 2–19; skip Part D fields 22–39 and proceed to Part E.

22. Organization Name	23. Organization FDA-Assigned FEI Number (if applicable)	24. Organization D&B DUNS® Number (if applicable)

25. Street Address Line 1	26. Street Address Line 2 *(Apt., Suite, Bldg., #)*

27. City	28. State, Province, or Territory	29. Country	30. ZIP or Postal Code

Point of Contact for Predicate Product(s) Manufacturer

31. First Name	32. Middle Initial	33. Last Name	34. Generational Suffix	35. Professional Suffix

36. Position Title	37. Phone Number	38. Fax Number	39. Email Address

Appendix C: Manufacturer/Packaging/Storage/Control Facility Information

Submit a single Form FDA 3965 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/Storage/Control Facility Information

1. Select type of site (select one):

☐ Manufacturer ☐ Contract manufacturer ☐ Repacker/relabeler ☐ Other _____

2. Alternate manufacturing site for:

☐ New product(s) manufacturer ☐ Predicate product(s) manufacturer ☐ Both new and predicate product(s) manufacturer

3. Organization Name	4. Organization FDA-Assigned FEI Number (if applicable)	5. Organization D&B DUNS® Number (if applicable)

6. Division Name (if applicable)

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 for Manufacturer/Packaging/Storage/Control Facility Information

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 D: Cross-Referenced Information

Submit a single Form FDA 3965 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-Referenced 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–IV)
	☐ 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 E: Referenced Tobacco Product Master File(s) (TPMF)

Submit a single Form FDA 3965 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 ☐ 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 ☐ 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 ☐ 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 ☐ 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 ☐ 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 ☐ 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 ☐ 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 ☐ 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 ☐ Yes ☐ No	

Appendix F: Formal Meetings Held with FDA Pertaining to the New Product(s)[2]

Submit a single Form FDA 3965 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 appropriate, completing all fields within each section.

1. Submission STN	2. Meeting Held Date *(mm/dd/yyyy)*	3. Is the content 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]):

Appendix G: Instructions for Completion of SE Form

This form and the instructions for use are solely intended to provide the applicant an organized format with which to supply information required for submission of a Substantial Equivalence (SE) Report.

Form FDA 3965 – Tobacco Substantial Equivalence Report Submission is a required form for applicants to use when submitting an SE Report 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 an SE submission, see 21 CFR 1107.18.

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/Packaging/Storage/Control Facility Information

Complete Field 1 for all applicants and proceed to Part A.

I.1. Select only one checkbox to indicate whether the applicant is a manufacturer or importer:

- Manufacturer – manufactures, fabricates, assembles, processes, or labels a tobacco product
  OR
- Importer – imports a finished tobacco product for sale or distribution in the United States

Part A: Applicant Information

Part A should include information regarding the applicant for the submission. An applicant may be a manufacturer or importer that submits an SE Report to receive marketing authorization for a new tobacco product. Part A should be completed for either an organization applicant or an individual applicant, NOT both.

Note: 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.

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 an SE 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-U-N-S® (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 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 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 submit date, or 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, 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) 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 submitting the application to FDA (e.g., submitting via the CTP Portal, the FDA Electronic Submissions Gateway [ESG], or handed to courier).
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, 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: Contact Information for the Authorized Representative or U.S. Agent

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 information is the same as the applicant information 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 an 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, 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, if applicable.

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, 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

Manufacturer (of New Product)

Part D fields 1–19 apply to the manufacturer of the ***NEW*** tobacco product. In field 1, indicate if the new product manufacturer is the same as the applicant (as identified in Section I Part A). If the same, skip Part D fields 2–19 and proceed to Part D field 20.

New Product(s) Manufacturer

I.D.1. Select the checkbox if the manufacturer (of the new product) and applicant information is the same. If the same, skip Part D fields 2–19.

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 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 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. 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.6. Additional street address information for the manufacturer location (including apartment, suite, building number, #) that you were not able to include in I.D.5.

I.D.7. The city where the manufacturer is located.

I.D.8. The state, province, or territory where the manufacturer is located.

I.D.9. The country where the manufacturer is located.

I.D.10. The ZIP or postal code where the manufacturer is located.

Point of Contact for New Product(s) Manufacturer

I.D.11. The first name of the manufacturer point of contact.

I.D.12. The middle initial of the manufacturer point of contact, if applicable.

I.D.13. The last name of the manufacturer point of contact.

I.D.14. The generational suffix (e.g., Jr., III) of the manufacturer point of contact, if applicable.

I.D.15. The professional suffix (e.g., M.D., Ph.D.) of the manufacturer point of contact, if applicable.

I.D.16. The professional position title of the manufacturer point of contact.

I.D.17. The phone number of the manufacturer point of contact (include country code if applicable and area code).

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

I.D.19. The email address of the manufacturer point of contact.

Predicate Product(s) Manufacturer

Part D fields 20–39 apply to the manufacturer of the ***PREDICATE*** tobacco product. In fields 20 and 21, indicate if the predicate product manufacturer is the same as the applicant (as identified in Section I Part A) or the new product manufacturer (as identified in Section I Part D fields 2–19). *Only* complete the rest of this section (fields 22–39) if the manufacturer of the predicate product is different from the applicant and different from the manufacturer of the new product.

I.D.20. Select the checkbox if the manufacturer of the predicate product and applicant information is the same. If the same, skip Part D fields 21–39.

I.D.21. Select the checkbox if the manufacturer of the predicate product and manufacturer of the new product information is the same. If the same, skip Part D fields 22–39.

I.D.22. 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.23. The manufacturer 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.24. The manufacturer 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.25. 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.26. Additional street address information for the manufacturer location (including apartment, suite, building number, #) that you were not able to include in I.D.25.

I.D.27. The city where the manufacturer is located.

I.D.28. The state, province, or territory where the manufacturer is located.

I.D.29. The country where the manufacturer is located.

I.D.30. The ZIP or postal code where the manufacturer is located.

Point of Contact for Manufacturer (of Predicate Product)

I.D.31. The first name of the manufacturer point of contact.

I.D.32. The middle initial of the manufacturer point of contact, if applicable.

I.D.33. The last name of the manufacturer point of contact.

I.D.34. The generational suffix (e.g., Jr., III) for the of the manufacturer point of contact, if applicable.

I.D.35. The professional suffix (e.g., M.D., Ph.D.) of the manufacturer point of contact, if applicable.

I.D.36. The professional position title of the manufacturer point of contact.

I.D.37. The phone number of the manufacturer point of contact (include country code if applicable and area code).

I.D.38. The fax number of the manufacturer point of contact, if applicable (include country code if applicable and area code).

I.D.39. The email address of the manufacturer point of contact.

Part E: Manufacturer/Packaging/Storage/Control Facility Information (Optional)

Use Part E to provide additional site information for the raw materials and/or components used in the manufacture of the finished new and/or predicate products (e.g., contract, processor of primary material, component fabricator, labeling service provider, repackaging by third party). Use the Continuation Page button within the form for additional sites, as needed.

For these fields, provide the following information for the Manufacturer/Packaging/Storage/Control Facility:

I.E.1. Select the appropriate checkbox to indicate the type of site.

I.E.2. Indicate if the additional manufacturing site is for the new product manufacturer, predicate product manufacturer, or both.

I.E.3. The organization name for the Manufacturer/Packaging/Storage/Control Facility (required by 21 CFR 1107.18(c)(8)).

I.E.4. The manufacturer FDA-assigned Facility Establishment Identifier (FEI) number, if applicable (required by 21 CFR 1107.18(c)(8)).
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.E.5. The manufacturer 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.6. The Manufacturer/Packaging/Storage/Control Facility division name, if applicable (required by 21 CFR 1107.18(c)(8)).

I.E.7. The street address for the Manufacturer/Packaging/Storage/Control Facility site (include street number, street name, and street type, and suffix direction, etc.) (required by 21 CFR 1107.18(c)(8)).

I.E.8. Additional street address information (including apartment, suite, building number, #) that you were not able to include in I.E.7. (required by 21 CFR 1107.18(c)(8)).

I.E.9. The city where the Manufacturer/Packaging/Storage/Control Facility is located (required by 21 CFR 1107.18(c)(8)). The street address cannot be a P.O. Box.

I.E.10. The state, province, or territory where the Manufacturer/Packaging/Storage/Control Facility is located (required by 21 CFR 1107.18(c)(8)).

I.E.11. The country where the Manufacturer/Packaging/Storage/Control Facility is located (required by 21 CFR 1107.18(c)(8)).

I.E.12. The ZIP or postal code where the Manufacturer/Packaging/Storage/Control Facility is located (required by 21 CFR 1107.18(c)(8)).

Point of Contact Information for Manufacturer/Packaging/Storage/Control Facility

For these fields, provide the following information for the Manufacturer/Packaging/Storage/Control Facility point of contact.

I.E.13. The first name of the Manufacturer/Packaging/Storage/Control Facility point of contact (required by 21 CFR 1107.18(c)(8)).

I.E.14. The middle initial of the Manufacturer/Packaging/Storage/Control Facility point of contact, if applicable (required by 21 CFR 1107.18(c)(8)).

I.E.15. The last name of the Manufacturer/Packaging/Storage/Control Facility point of contact (required by 21 CFR 1107.18(c)(8)).

I.E.16. The generational suffix (e.g., Jr., III) of the Manufacturer/Packaging/Storage/Control Facility point of contact, if applicable.

I.E.17. The professional suffix (e.g., M.D., Ph.D.) of the Manufacturer/Packaging/Storage/Control Facility point of contact, if applicable.

I.E.18. The position title of the Manufacturer/Packaging/Storage/Control Facility point of contact, if applicable (required by 21 CFR 1107.18(c)(8)).

I.E.19. The phone number of the Manufacturer/Packaging/Storage/Control Facility point of contact (include country code if applicable and area code) (required by 21 CFR 1107.18(c)(8)).

I.E.20. The fax number of the Manufacturer/Packaging/Storage/Control Facility point of contact, if applicable (include country code if applicable and area code) (required by 21 CFR 1107.18(c)(8)).

I.E.21. The email address of the Manufacturer/Packaging/Storage/Control Facility point of contact (required by 21 CFR 1107.18 (c)(8)).

SECTION II — NEW TOBACCO PRODUCT INFORMATION

Use Form FDA 3965b - Tobacco Substantial Equivalence Report Unique Identifying Information for New Tobacco Product Spreadsheet available on the FDA website to provide new and predicate product information.

SECTION III – PREDICATE PRODUCT ELIGIBILITY

Part A: Predicate Product(s) Status

III.A.1. Indicate how the predicate product(s) are eligible to serve as a predicate product for the new product(s). Select all that apply.

- **Previously Found SE** – Select the checkbox if the predicate products were previously found to be substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act. If only Previously Found SE is selected, skip Section III, Part B.
- **PTP Determined** – Select the checkbox if the predicate products identified in Form FDA 3965b were submitted for pre-existing tobacco product (PTP) review independently of these SE Reports, were determined to be PTP and found eligible to serve as predicate products. FDA previously used the term “grandfathered product” to describe a product that was commercially marketed in the United States (other than in a test market) as of February 15, 2007. However, on November 4, 2021, FDA updated the term “grandfathered tobacco product” (GF) to “pre-existing tobacco product” (PTP). If only PTP Determined is selected, skip Section III, Part B; complete the I. Certification Statement of Affirmation in Section VI.
- **Claimed PTP** – Select the checkbox if the predicate products were not previously submitted for PTP review and were not previously found to be substantially equivalent as above, but you believe the predicates products are pre-existing tobacco products. Complete Part B and the I. Certification Statement of Affirmation in Section VI.

Part B: Predicate Product Evidence

Use this section only if the predicate has not been previously reviewed by FDA.

Evidence of Commercial Marketing as of February 15, 2007

For these fields, provide the following information regarding the evidence of commercial marketing:

- **III.B.1.** The type of evidence (e.g., Invoice, catalog pages, distributor or retailer inventory lists).
- **III.B.2.** The date of evidence.
- **III.B.3.** The identifier of the evidence (e.g., Invoice Number).
- **III.B.4.** The commercial information (e.g., UPC code, product description, item number).
- **III.B.5.** List the predicate product name(s) as indicated by the evidence provided for field III.B.1.

Business Addresses Associated with Evidence of Commercial Marketing (Optional)

For these fields, provide the address(es) as reflected in the evidence demonstrating commercial marketing:

- **III.B.6.** The street address of the physical location of the business (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.
- **III.B.7.** Additional street address information for the business (including apartment, suite, or building number) that you were not able to include in III.B.6.
- **III.B.8.** The city of the business.
- **III.B.9.** The state, province, or territory of the business.
- **III.B.10.** The country of the business.
- **III.B.11.** The ZIP or postal code of the business.
- **III.B.12.** The street address of the physical location of the business (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.
- **III.B.13.** Additional street address information for the business (including apartment, suite, or building number) that you were not able to include in III.B.12.
- **III.B.14.** The city of the business.
- **III.B.15.** The state, province, or territory of the business.
- **III.B.16.** The country of the business.
- **III.B.17.** The ZIP or postal code of the business.

SECTION IV – SUBMISSION INFORMATION

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

- Part A: General Submission Information
- 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

For grouped submissions, the application type must be the same and the proposed modification(s) to the new tobacco products (as compared to the predicate tobacco product[s]) should be similar. If application type is **not** the same and/or proposed modification are not similar, submit a separate Form FDA 3965.

- **IV.A.1.** Select only one checkbox to indicate whether the application type is Same Characteristics (such as changes in product quantity or changes in container closure system) Reports or Different Characteristics Reports.

IV.A.2. Summarize the submission, as described in 21 CFR 1107.18(d), with a concise description of the characteristics of the new tobacco product; a statement as to whether the applicant believes the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics but any differences in characteristics do not cause the new tobacco product to raise different questions of public health; and a concise description of the similarities and differences between the new tobacco product and the predicate tobacco product with respect to their characteristics (materials, ingredients, design, composition, heating source, or other features).

IV.A.3. Select all checkboxes that apply to indicate proposed modification(s) to the new tobacco product(s) compared to the predicate tobacco product(s).

Part B: Cross-Referenced Information (Optional)

Complete Part B if the application includes one or more cross-reference(s) to a standalone PTP submission or authorized SE submission other than the predicate product listed in Form FDA 3965b. SE Reports should not cross-reference other pending SE applications. 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.

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

IV.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.

IV.B.3. In column 3, identify what information in the cross-referenced 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).

Boxes 1–5 should be provided for each TPMF. Use the Continuation Page button within the form for additional TPMFs, as needed.

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

IV.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.”

IV.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.

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

IV.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 the 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) (If Applicable)

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.

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

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

IV.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 V – APPLICATION CONTENTS

Section V is intended to help applicants organize their submission per 21 CFR 1107.18. 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

V.A.1. Cover Letter.

V.A.2. Comprehensive Index (i.e., a listing of files and data associated with those files) and Table of Contents (21 CFR 1107.18(b)).

V.A.3. Unique Identification of new tobacco product(s) and predicate tobacco product(s) must be provided in FDA form 3965b available on the FDA website.

V.A.4. Written in English or accompanied by an English translation for non-English information (21 CFR 1107.18(b)). 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.

Part B: Product Information

V.B.1. List of Ingredients – The SE Report must include, in a tabular format, a side-by-side comparison of the materials and ingredients for each component or part of the new and predicate tobacco products. For each material and ingredient quantity, the target specifications and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part, must be provided (21 CFR 1107.19(c)).

V.B.2. Information on Manufacturing Process – A concise overview of the process used to manufacture the new tobacco product. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy this provision (21 CFR 1107.18(e)(3)).

V.B.3. Statement of compliance with applicable tobacco product standards – The SE Report must either list and describe the action(s) taken by the applicant to comply with applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act or state there are no applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act (21 CFR 1107.18(i)).

Part C: Health and Research

Select only one checkbox in Part C to indicate whether the application contains a Health Information Summary or Health Information Statement, as required by 21 CFR 1107.18(j).

V.C.1. Select this checkbox if the application includes a Health Information Summary.

V.C.2. Select this checkbox if the application includes a Health Information Statement. A copy of the required statement can be found in Section VI for signature.

Part D: Comparisons (New vs. Predicate Tobacco Product)

V.D.1. Product Design as described in 21 CFR 1107.19(a).

V.D.2. Heating Source as described in 21 CFR 1107.19(b).

V.D.3. Composition (e.g., materials, tobacco ingredients, non-tobacco ingredients) per 21 CFR 1107.19(c).

V.D.4. Other features (e.g., HPHCs). If there are other features that are not HPHCs, please describe in the "Other" field per 21 CFR 1107.19(d).

V.D.5. Stability as described in 21 CFR 1107.19(f).

V.D.6. Comparison to Original Predicate Tobacco Product – Select this checkbox only if you are using a predicate tobacco product that FDA has previously found to be SE, and you have provided a comparison of the new product and the original previously found SE predicate tobacco product per 21 CFR 1107.19(h).

Part E: Environmental Considerations

V.E.1. Environmental Assessment as described in 21 CFR 25.40 and 21 CFR 1107.18(k)(2).

V.E.2. Claim for Categorical Exclusion as described in 21 CFR Part 25.35.

SECTION VI – CERTIFICATION STATEMENTS

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

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

i. **Certification Statement of Affirmation** is required for all SE Reports that use a pre-existing tobacco product (PTP) determined or a PTP claimed predicate product.

- Provide the name of the applicant being represented in the certification, as identified in Section I Part A .
- List the predicate product names subject to the Statement of Affirmation.

ii. **Certification Statement for SE Report** is required for all SE Reports.

- Provide the name of authorized representative signing the certification, as identified in Section I Part A.
- Provide the name of the applicant being represented in the certification, as identified in Section I Part A *(twice).*

iii. **Certification Statement for Same Characteristics SE Report** is appropriate when submitting a Same Characteristics SE Report and choosing to certify that certain characteristics are identical **in lieu of providing data** for each characteristic of the new and predicate products.

- Provide the name of the authorized representative signing the certification, as identified in Section I Part A.
- Provide the name of the applicant being represented in the certification, as identified in Section I Part A *(twice).*
- Provide the name(s) of the individual new and predicate product(s), as identified in Section II.
- Provide a description of the modifications, as identified in Section IV Part A.
  Note: If submitting a grouped submission, a certification statement is needed for each new product. These can be provided as a separate document from Form FDA 3965.

iv. **Certification Statement Regarding Availability of Health Information** is appropriate when choosing to make health information available upon request as per 21 CFR 1107.18(j)(2) rather than including a health information summary with their SE Report.

- Provide the name of the authorized representative signing the certification, as identified in Section I Part A.
- Provide the professional position title held by the authorized representative as identified in Section I Part A
- Provide the name of the company of the authorized representative.

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

If you choose to print and wet sign the certification statements, upload them as a separate document from Form FDA 3965 to maintain the dynamic fields in Adobe and ensure all content is available for FDA to process, read, review, and archive.