DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TOBACCO SUBSTANTIAL EQUIVALENCE REPORT AMENDMENT AND GENERAL CORRESPONDENCE SUBMISSION

Form Approved: OMB No. 0910-0673
Expiration Date: xx/xx/20xx

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 the Appendix before completing this form.

SECTION I – APPLICANT IDENTIFICATION[1]

Part A: Applicant Information[2]

The applicant is the individual or organization (manufacturer/importer) seeking a marketing granted order for a new product. 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.

1. Organization Name	2. Other Organization Names (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

If applicant is an individual, complete 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., #)*

[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.

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: Submission Type

1. Identify the type of submission (select one):

☐ **Amendment** (*if selected, proceed to Section II*)

☐ **General Correspondence** *(if selected, skip Section II and proceed to Section III)*

SECTION II – AMENDMENT INFORMATION

Part A: Amendment Purpose

1. List the FDA Submission Tracking Number (STN) and Product Identifier (PD) Number, or STN.PD# (e.g., SE5679840.PD1), assigned to the application being amended:

2. Select the subject(s) of the amendment *(select all that apply*):

☐ Response to Deficiency Letter

☐ Response to Environmental Information Request Letter

☐ Response to Information Request Letter

☐ Request for Extension of Time to Respond to Deficiency Letterr

☐ Request to Withdraw the SE Report
–If selected, provide the name and STN.PD# of product(s) being withdrawn:

☐ Select to indicate that the withdrawal is due to a health or safety concern related to the tobacco product.

☐ Update to Unique Identification Information
–If selected, you must provide FDA Form 3965b for any amended product properties with this submission and an STN.PD# in Additional Properties.

☐ Update Product Properties
–If selected, provide updates in Section II.C below.

☐ Submit Adverse Experience Report
–If selected, provide submission summary in Section II.A.3 below.

☐ Change in Cross-Referenced Content .

☐ Change in Related Submissions

☐ Change in Tobacco Product Master File Referenced

☐ Letter of Authorization (LOA)

☐ Change in Submission Contents
–If selected, provide submission summary in Section II.A.3 below.

☐ Other
–If selected, provide submission summary in Section II.A.3 below.

3. Summarize the submission in the space provided, if you selected "Submit Adverse Experience Report," "Change in Submission Contents," or "Other" in Section II.A.2:

Part B: Predicate Product Evidence
(Complete only if the predicate has not been previously reviewed by CTP)

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 from) Street Address Line 2 *(Apt., Suite, Bldg., #)*
14. City	15. State, Province, or Territory	16. Country	17. ZIP or Postal Code

Part C: Update to Product Properties (if applicable)

Use this section if you selected "Update Product Properties" in Section II.A.2 and you are amending previously submitted product property information

Update to New Product Properties

1. New Product Name	2. STN. PD#	3. Action	4. Property Name	5. Previously Submitted Target Value	6. Updated Target Value
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			

Continuation Page for Update to New Product Properties

Update to Predicate Product Properties

7. Predicate Product Name	8. STN. PD#	9. Action	10. Property Name	11. Previously Submitted Target Value	12. Updated Target Value
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			

Continuation Page for Update to Predicate Product Properties

Part D: Cross-Referenced Information (Optional)

Use this section if you selected "Change in Cross-Referenced Content" in Section II.A.2 and you are adding, updating, or removing any cross-referenced content.

1. Cross-Referenced STN	2. Action	3. Is the content relevant to all product(s) within this submission?	4. Information and sections to be referenced
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	

Continuation Page for Cross-Referenced Content

Part E: Related Submissions

Use this section if you selected "Change in Related Submissions" in Section II.A.2 and you are adding, updating, or removing any related submissions content.

1. Related Submission(s) STN	2. Action	3. Is the content relevant to all product(s) within this submission?	4. Information and sections to be referenced
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	

Continuation Page for Related Submissions

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

Use this section if you selected "Change in Tobacco Product Master File Referenced" in Section II.A.2 and you are adding, updating, or removing any referenced TPMFs. Complete fields 1–6 for each amended TPMF cross-reference. Use the Continuation Page button below to list additional TPMFs.

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

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

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

Continuation Page for Referenced TPMF

Part G: Amendment Contents

This amendment contains the following items (provide description and indicate file name and location of amendment content):

1. _____

   Location: _____

2. _____

   Location: _____

3. _____

   Location: _____

4. _____

   Location: _____

5. _____

   Location: _____

6. _____

   Location: _____

7. _____

   Location: _____

8. _____

   Location: _____

Part H: Certification Statements

Insert the name of the authorized representative(s) or U.S. agent and the name of the organization being represented in the body of the statement.

i. Certification Statement of Affimation

I, *(name and position title 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(s) of predicate tobacco product(s)

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

ii. Certification Statement for SE Report:

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)*

SECTION III – GENERAL CORRESPONDENCE INFORMATION

Submission Information for General Correspondence

1. Subject of Correspondence *(select all that apply)*:

☐ Change in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact
–If selected, complete Section III Part A below.

☐ Request for Change in Ownership
–If selected, complete Section III Part B below.

☐ Submit Adverse Experience Report
–If selected, provide submission summary in Section III field 2 below.

☐ Request to Withdraw Previously Submitted General Correspondence
–If selected, provide submission summary in Section III field 2 below.

☐ Meeting Request
–If selected, complete Section III Part C below.

☐ Other
–If selected, provide submission summary in Section III field 2 below.

2. Summarize the correspondence in the space provided if you selected "Submit Adverse Experience Report," "Request to Withdraw Previously Submitted General Correspondence," or "Other" in Section III field 1:

Part A: Add, Update, or Remove Applicant Information or Point of Contact (Optional)

Complete this section if you selected "Change in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact Information" in Section III field 1 and you are updating previously submitted contact information. Use the Continuation Page button below to list additional changes in applicant information or points of contact.

1. Select only one:

Choose an action

–If "Update" is selected, provide a brief description of the update here:

2. Select the type of contact *(select one):*

☐ Applicant ☐ Authorized Representative ☐U.S. Agent
(Address and contact information only)

☐ Manufacturer ☐ Contract Manufacturer ☐ Repacker/Relabeler ☐ Other_____

3. Is this change applicable for all current FDA submissions?

☐ Yes ☐ No *(list applicable STNs.PD#s):*

4. Effective Date of Change *(mm/dd/yyyy)*

Current Contact Information on Record					***Added/Updated Contact Information***				
5. First Name	6. Middle Initial	7. Last Name			23. First Name	24. Middle Initial	25. Last Name		
8. Generational Suffix	9. Professional Suffix				26. Generational Suffix	27. Professional Suffix			
10. Position Title					28. Position Title				
11.Organization Name					29.Organization Name				
12. Organization FDA-Assigned Facility Establishment Identifier (FEI) Number	13. Organization D&B DUNS® Number				30. Organization FDA-Assigned Facility Establishment Identifier (FEI) Number	31. Organization D&B DUNS® Number			
14. Street Address Line 1	15. Street Address Line 2 *(Apt., Suite, Bldg., #)*				32. Street Address Line 1	33. Street Address Line 2 *(Apt., Suite, Bldg., #)*			

Current Contact Information on Record (cont.)		*Added/Updated Contact Information (cont.)*	
16. City	17. State, Province, or Territory	34. City	35. State, Province, or Territory
18. Country	19. ZIP or Postal Code	36. Country	37. ZIP or Postal Code
20. Phone Number	21. Fax Number	38. Phone Number	39. Fax Number
22. Email Address		40. Email Address	

Continuation Page for Part A

Part B: Request for Change in Ownership

Complete this section if you selected "Request for Change in Ownership" in Section III Submission for General Correspondence field 1 and the correspondence includes a request for a change in ownership.

1. Applications, submissions, and product names to be transferred including the FDA Submission Tracking Number and Product Identifier PD Number (STN.PD#):
   (Optional: Applicants may provide a separate list of submissions subject to transfer)

STN	**PD Number** *(if applicable)*	**Product Name** *(if applicable)*

2. Effective Date of Change *(mm/dd/yyyy)*

3. This transfer request contains the following items *(select all that apply):*

- ☐ A signed transfer of ownership request letter from the **former** applicant must include:
  - ☐ The specific applications, submissions, and product names by STN being transferred.
  - ☐ A statement that all rights of the applications have been transferred to the new applicant.
  - ☐ Contact information for the new applicant (name, mailing address, phone number, and email).
- ☐ A signed letter from the **new** applicant accepting the change in ownership from the former applicant must include:
  - ☐ The specific applications, submissions, and product names by STN being accepted.
  - ☐ A statement committing to all agreements, promises, and conditions made by the former applicant of record contained in the applications and submissions.
  - ☐ A statement that the new applicant has a complete copy of the applications and submissions including amendments and records that are required to be kept, or state they will request a copy per 21 CFR 20.40.
  - ☐ A statement that no modifications have been made to the transferred tobacco applications and submissions.
  - ☐ Contact information for the new applicant (name, mailing address, phone number, and email).

Continuation Page for Part B

Part C: Meeting Request

Complete this section if you selected "Meeting Request" in Section III Submission for General Correspondence field 1 and the correspondence includes a meeting request.

1. Meeting Topic
2. Meeting Purpose
3. Meeting Format
4. Is the meeting information package included? ☐ Yes ☐ No *(provide expected date of submission (mm/dd/yyyy)):* _____

Continuation Page for Part C

Products to be Discussed at Meeting

5. Product Name	**6. Product Use**	**7. Product Category** *(if applicable)*	**8. STN.PD#** *(if applicable)*
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	

9. This meeting request contains the following items *(select all that apply):*

☐ A preliminary list of the specific objectives/outcomes expected from the meeting.

☐ A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item.

☐ A preliminary list of specific critical questions, grouped by discipline (e.g., chemistry, clinical, non-clinical).

☐ A list of all individuals who will attend the meeting on your behalf, including titles and responsibilities.

SECTION VII – APPENDICES

CONTINUATION PAGES

Appendix A: Update to Product Properties (if applicable)

Submit a single Form FDA 3965a 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 II, Part C: Update to Product Properties (if applicable)

Update to New Product Properties

1. New Product Name	2. STN. PD#	3. Action	4. Property Name	5. Previously Submitted Target Value	6. Updated Target Value
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			

Update to Predicate Product Properties

7. Predicate Product Name	8. STN. PD#	9. Action	10. Property Name	11. Previously Submitted Target Value	12. Updated Target Value
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			
		Choose an action			

Appendix B: Cross-Referenced Content

Submit a single Form FDA 3965a 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 II, Part D: Cross-Referenced Content

1. Cross-Referenced STN	2. Action	3. Is the content relevant to all product(s) within this submission?	4. Information and sections to be referenced
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	

Appendix C: Related Submissions

Submit a single Form FDA 3965a 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 II, Part E: Related Submissions

1. Related Submission(s) STN	2. Action	3. Is the content relevant to all product(s) within this submission?	4. Information and sections to be referenced
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	
	Choose an action	☐ Yes ☐ No (list applicable product name[s]):	

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

Submit a single Form FDA 3965a 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 III, Part F: Referenced Tobacco Product Master File(s) (TPMF)

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

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

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

Appendix E: Add, Update, or Remove Applicant Information or Point of Contact (Optional)

Submit a single Form FDA 3965a 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 III, Part A: Add, Update, or Remove Applicant Information or Point of Contact (Optional)

1. Select only one:

Choose an action

–If "Update" is selected, provide a brief description of the update here:

2. Select the type of contact *(select one):*

☐ Applicant ☐ Authorized Representative ☐U.S. Agent
(Address and contact information only)

☐ Manufacturer ☐ Contract Manufacturer ☐ Repacker/Relabeler ☐ Other_____

3. Is this change applicable for all current FDA submissions?

☐ Yes ☐ No *(list applicable STNs.PD#s):*

4. Effective Date of Change *(mm/dd/yyyy)*

Current Contact Information on Record		
5. First Name	6. Middle Initial	7. Last Name
8. Generational Suffix	9. Professional Suffix	
10. Position Title		
11.Organization Name		
12. Organization FDA-Assigned Facility Establishment Identifier (FEI) Number	13. Organization D&B DUNS® Number	

Added/Updated Contact Information		
23. First Name	24. Middle Initial	25. Last Name
26. Generational Suffix	27. Professional Suffix	
28. Position Title		
29.Organization Name		
30. Organization FDA-Assigned Facility Establishment Identifier (FEI) Number	31. Organization D&B DUNS® Number	

Current Contact Information on Record (cont.)		*Added/Updated Contact Information (cont.)*	
14. Street Address Line 1	15. Street Address Line 2 *(Apt., Suite, Bldg., #)*	32. Street Address Line 1	33. Street Address Line 2 *(Apt., Suite, Bldg., #)*
16. City	17. State, Province, or Territory	34. City	35. State, Province, or Territory
18. Country	19. ZIP or Postal Code	36. Country	37. ZIP or Postal Code
20. Phone Number	21. Fax Number	38. Phone Number	39. Fax Number
22. Email Address		40. Email Address	

Appendix F: Request for Change in Ownership (Optional)

Submit a single Form FDA 3965a 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 III, Part B: Request for Change in Ownership

1. Applications, submissions, and product names to be transferred including the FDA Submission Tracking Number and Product Identifier PD Number (STN.PD#):
   (Optional: Applicants may provide a separate list of submissions subject to transfer)

STN	PD Number *(if applicable)*	Product Name *(if applicable)*

Appendix G: Meeting Request

Submit a single Form FDA 3965a 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 III, Part C: Meeting Request

Products to be Discussed at Meeting

5. Product Name	6. Product Use	7. Product Category *(if applicable)*	8. STN.PD# *(if applicable)*
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	
	Choose an item	Choose a product category	

Appendix H: Instructions for Completion of SE Amendment and General Correspondence Submission Form

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

Form FDA 3965A – Tobacco Substantial Equivalence (SE) Report Amendment and General Correspondence Submission is a required form for applicants submitting SE amendments or other general correspondence 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.

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: Submission Type

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, 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) 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, 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: Submission Type

I.B.1. Select only one checkbox to indicate the type of submission:

- Amendment – *if selected, proceed to Section II*
- General Correspondence – *if selected, skip Section II and proceed to Section III*

Note: If you need to submit both an amendment and general correspondence, include two separate forms.

SECTION II — AMENDMENT INFORMATION

Complete Section II if you selected "Amendment" as the submission type in Section I.B.1.

Part A: Amendment Purpose

II.A.1. List the SE Report(s) being amended in the space provided; include the FDA Submission Tracking Number (STN) and Product (PD) Identifier, or STN.PD # (e.g., SE5679840.PD1).

II.A.2. Indicate the subject(s) of the amendment (select all that apply).

Note: If you select "Request to Withdraw the SE Report," provide the product name and STN.PD# of the products to be withdrawn and select the additional checkbox if the withdrawal is due to a health or safety concern related to the tobacco product. If you select "Update to Unique Identification Information," submit Form FDA 3965b with the STN.PD# in additional properties. If you select "Update Product Properties," proceed to Section II.C.

II.A.3. Summarize the submission in the space provided if you selected one of the following options in Section II.A.2:

- Submit Adverse Experience Report
- Change in Submission Contents
- Other

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 evidence of commercial marketing (as of February 15, 2007)

- **II.B.1.** The type of evidence (e.g., invoice).
- **II.B.2.** The date of evidence (in the format of mm/dd/yyyy).
- **II.B.3.** The evidence identifier (e.g., invoice number).
- **II.B.4.** The commercial information (e.g., UPC code, product description, item number).
- **II.B.5.** The product quantity (as indicated by the evidence).

Business Addresses Associated with Evidence of Commercial Marketing (optional):

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

- **II.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.
- **II.B.7.** Additional street address information for the business (including apartment, suite, or building number) that you were not able to include in II.B.6.
- **II.B.8.** The city of the business.
- **II.B.9.** The state, province, or territory of the business.
- **II.B.10.** The country of the business.
- **II.B.11.** The ZIP or postal code of the business.
- **II.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.
- **II.B.13.** Additional street address information for the business (including apartment, suite, or building number) that you were not able to include in II.B.12.
- **II.B.14.** The city of the business.
- **II.B.15.** The state, province, or territory of the business.
- **II.B.16.** The country of the business.
- **II.B.17.** The ZIP or postal code of the business.

Part C: Update to Product Properties (if Applicable)

Complete Part C if you selected “Update Product Properties” in Section II.A.2 to amend previously submitted product property information. This section is **not** for submitting changes to Unique Identification Information (see Section II.A).

Update(s) to New Product(s):

Within this table, utilize a single row for each update to a new product. Use the Continuation Page button within the form to provide additional updates, as needed.

- **II.C.1.** The name of the new product.
- **II.C.2.** The STN.PD# for the new product, or FDA Submission Tracking Number (STN) and Product (PD)Identifier.
- **II.C.3.** Choose an option from the dropdown to indicate an action: add, update, or remove (previously submitted new product property information).
- **II.C.4.** The name of the property.
- **II.C.5.** The previously submitted target value.
- **II.C.6.** The updated target value.

Update(s) to Predicate Product(s):

Within this table, utilize a single row for each update to a predicate product. Use the Continuation Page button within the form to provide additional updates, as needed.

II.C.7. The name of the predicate product.

II.C.8. The STN.PD# for the predicate product, or FDA Submission Tracking Number (STN) and Product (PD) Identifier.

II.C.9. Choose an option from the dropdown to indicate an action: add, update, or remove (previously submitted predicate product property information).

II.C.10. The name of the property.

II.C.11. The previously submitted target value.

II.C.12. The updated target value.

Part D: Cross-Referenced Content

Complete Part D if you selected "Change in Cross-Referenced Content" in Section II.A.2 for the addition, update, or removal of any cross-referenced content. 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.

II.D.1. Provide the FDA submission tracking number (STN) for the cross-referenced submission.

II.D.2. Choose an option from the dropdown to indicate an action: add, update, or remove (the cross-referenced content).

II.D.3. 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.

II.D.4. 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 E: Related Submissions

Complete Part E if you selected "Change in Related Submissions" in Section II.A.2 for the addition, update, or removal of any related submissions. Within the table, utilize a single row for each related submission. Use the Continuation Page button within the form to provide additional related submissions, as needed.

II.E.1. The FDA submission tracking number (STN) for the related submission.

II.E.2. Choose an option from the dropdown to indicate an action: add, update, or remove (the related submission).

II.E.3. Identify if the related submission provided in column 1 is for all products in the submission. If the related submission only applies to some of the new products in the submission, select "no" and list the name of the product(s) that reference the related submission.

II.E.4. The location within the related submission that you are seeking to reference for your new submission. For example, list the specific file name, document name, and page number.

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

Complete Part F if you selected "Change in Tobacco Product Master File Referenced" in Section II.A.2 for the addition, update, or removal of any referenced TPMFs. Complete one table (fields 1–6) for each TPMF. Use the Continuation Page button within the form to provide additional TPMFs, as needed.

II.F.1. Identify the TPMF owner.

II.F.2. Provide the FDA 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."

II.F.3. Choose an option from the dropdown to indicate an action: add, update, or remove (the TPMF).

II.F.4. 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.

II.F.5. Identify what information in the TPMF you are seeking to reference for the new submission(s) and which sections in the TPMF are being referenced (e.g., all sections of the TPMF, sections I–III of the TPMF).

II.F.6. 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 G: Amendment Contents

Complete Part G to describe the items included in this amendment. For each item, provide a description of the content and indicate the file name and location of the content.

Part H: Certification Statements

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

i. **Statement of Affirmation**
   - Complete the Statement of Affirmation by providing the name and position title of the responsible official.
   - The name(s) of the predicate tobacco product(s) to which the Statement of Affirmation would apply.
   - Insert the signature of the responsible official and the date the statement is signed.

ii. **Certification Statement for Standard SE Reports** is required for all SE Reports.
   - Provide the name of the responsible official, or the authorized representative who is signing the certification.
   - Provide the name of the applicant being represented in the certification. Insert the name of the applicant as identified in Section I, Part A.
   - Provide the signature of the authorized representative of the applicant and the current date.

SECTION III – GENERAL CORRESPONDENCE INFORMATION

Complete Section III if you selected "General Correspondence" as the submission type in Section I.B.1.

Submission Information for General Correspondence

III.1. Select the checkbox(es) to indicate the subject(s) of the Correspondence.

III.2. Summarize the submission in the space provided, if you selected one of the following options in Section III.1.
- Submit Adverse Experience Report
- Request to Withdraw Previously Submitted General Correspondence
- Other

Part A: Add, Update, or Remove Applicant Information or Point of Contact (Optional)

Complete Part A if you selected "Change in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact" in Section III.1. for the addition, update, or removal of contact/address information for the applicant or another point of contact. Use the Continuation Page button within the form to list additional contact information updates, as needed.

III.A.1. Select only one option from the dropdown to indicate an action: add, update, or remove (the contact/address information).

- Add – *Select to add a new party; if "Add" is selected, provide all contact information for the new party in fields 23–40. FDA may contact this new party to discuss the submission.*
- Update – *Select to change the contact information for an existing party; if "Update" is selected, provide the contact information as previously provided to FDA in fields 5–22 and the updated contact information in fields 23–40. FDA will update the Applicant Identification address or contact information that was previously submitted based on the updated information in field 23-40.*
    - Additionally, provide a brief description of the update in the space provided.
- Remove – *Select to request that FDA remove an existing party on record. If "Remove" is selected, provide only the name of the party (Person's Name and/or Organization's Name) to be removed in fields 5–7 and/or 11. FDA will no longer contact the removed party to discuss to the submission.*

III.A.2. Select only one checkbox to indicate the type of contact whose information should be added updated/removed.

III.A.3. Indicate whether this change is applicable for all current FDA submissions. If the change is only for some current submissions, select "no" and list the STN.PD#s that this change is applicable to.

III.A.4. Indicate the date of the effective change.

Complete fields 5–22 with contact information for the current, existing party.

III.A.5. The first name of the current party.

III.A.6. The middle initial of the current party, if applicable.

III.A.7. The last name of the current party.

III.A.8. The generational suffix (e.g., Jr., III) for the current party, if applicable.

III.A.9. The professional suffix (e.g., M.D., Ph.D.) for the current party, if applicable.

III.A.10. The professional position title of the current party.

III.A.11. The organization name representing the current party.

III.A.12. 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.

III.A.13. The organization D&B DUNS number, if applicable.

III.A.14. The street address for the current party (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.

III.A.15. Additional street address information for the current party (including apartment, suite, or building number) that you were not able to include in III.A.14.

III.A.16. The city of the current party.

III.A.17. The state, province, or territory of the current party.

III.A.18. The country of the current party

III.A.19. The ZIP or postal code of the current party.

III.A.20. The phone number of the current party (include country code, if applicable, and area code).

III.A.21. The fax number of the current party, if applicable (include country code, if applicable, and area code).

III.A.22. The email address of the current party.

Complete fields 23–40 with contact information for the new/updated party.

III.A.23. The first name of the new party.

III.A.24. The middle initial of the new party, if applicable.

III.A.25. The last name of the new party.

III.A.26. The generational suffix (e.g., Jr., III) for the new party, if applicable.

III.A.27. The professional suffix (e.g., M.D., Ph.D.) for the new party, if applicable.

III.A.28. The professional position title of the new party.

III.A.29. The organization name representing the new party.

III.A.30. 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.

III.A.31. The organization D&B DUNS number, if applicable.

III.A.32. The street address for the new party (including street number, street name and type, suffix direction, etc.). The street address cannot be a P.O. Box.

III.A.33. Additional street address information for the new party (including apartment, suite, or building number) that you were not able to include in III.A.32.

III.A.34. The city of the new party.

III.A.35. The state, province, or territory of the new party.

III.A.36. The country of the new party.

III.A.37. The ZIP or postal code of the new party.

III.A.38. The phone number of the new party (include country code, if applicable, and area code).

III.A.39. The fax number of the new party, if applicable (include country code, if applicable, and area code).

III.A.40. The email address of the new party.

Part B: Request for Change in Ownership

Complete Part B if you selected "Request for Change in Ownership" in Section III.1. Use the Continuation Page button within the form to list additional applications, submissions, and/or product names to be transferred, as needed.

A change in or transfer of ownership is for applicants (companies) that manufacture or sell tobacco products and transfers the rights and responsibilities for their applications and submissions to another company. The **former applicant** is the party that is listed in FDA's records to date. The **new applicant** is the party taking responsibility for the submissions. The new and former applicant must sign and submit certain information and statements to complete the transfer. This information is submitted as a general correspondence for all applications/submissions and not as an amendment to each application. The former applicant and new applicant must submit all information as outlined in Section III, Part B as applicable to their role in the transfer.

> *Note*: The former applicant may select checkboxes for former and new if they are submitting all requirements on behalf of both parties. The new applicant **cannot** submit on behalf of the former. FDA will only process the request for change in ownership upon receipt of the request from the **former applicant**.

For change in ownership requests that include Premarket Tobacco Product Applications (PMTA) or Substantial Equivalence (SE) Reports, FDA Form 4057a and/or FDA Form 3965a are required. A single form can be provided for transfer requests that include multiple submission types. Changes in ownership that do not include SE or PMTA submissions do not require FDA Form 4057a or FDA Form 3965a, though we encourage the use of forms.

The following are submission types that FDA will transfer:

- Marketing Applications
  - 910 Premarket Tobacco Application (PMTA)
  - 905(j)(1) Substantial Equivalence Reports (SE)
  - 905(j)(3) Exemption from Substantial Equivalence (EX)
  - 911 Modified Risk Tobacco Product Application (MRTPA)
- Submissions
  - 910(g) Investigational Tobacco Use (IU)
  - General Correspondence and Meeting Requests (TC)
  - Master Files (MF)
  - Grandfather Determination Requests (GF)
  - Pre-Existing Tobacco Products (PX)
  - Warning Plans (WP)
  - Other Media Notifications (OM)

III.B.1. Indicate the applications, submissions, and product names to be transferred, including the STN, PD numbers, and product names.

III.B.2. Indicate the effective date of the transfer.

III.B.3. Select the checkbox(es) to indicate the items included in the transfer request.

Part C: Meeting Request

Complete Part C if you selected “Meeting Request” in Section III.1. This is a request for a formal meeting which may include topics such as study design, earlier versions of the product, etc. Use the Continuation Page button within the form to list additional products, as needed.

III.C.1. The topic of the meeting.
III.C.2. The purpose of the meeting.
III.C.3. The format of the meeting.
III.C.4. Indicate whether the meeting information package is included. If not, select “No” and provide the expected date of the submission.
III.C.5. List the name of the product(s) to be discussed at the meeting.
III.C.6. The use of the product.
III.C.7. The product category (if applicable).
III.C.8. The STN.PD# of the product (if applicable).
III.C.9. Select the checkbox(es) to indicate the items included in the meeting request.