DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission

Form Approved: OMB No. xxxx-xxxx
Expiration Date: xx/xx/202x
(See Burden Statement on last page.)

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

STATUTORY REQUIREMENTS

Section 910(a)(1) of the FD&C Act – Defines a new tobacco product as "(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." (Pre-Existing Tobacco Product) (PTP)

Section 910(a)(2) of the FD&C Act – Premarket review required for new tobacco products. There are three pathways to achieve marketing authorization. Substantial Equivalence is one of the three pathways.

Section 910(a)(3) of the FD&C Act – "Substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product ''(i) has the same characteristics as the predicate tobacco product; or (ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health."

Section 905(j)(1)(A)(i) of the FD&C Act – Includes the time frame and basis for submission of a Substantial Equivalence Report (SE Report).

This section is deliberately blank.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission

Form Approved: OMB No. xxxx-xxxx
Expiration Date: xx/xx/202x
(See Burden Statement on last page.)

The Applicant Identification section is comprised of three parts: Current Applicant Information; Request to Change Ownership; and the Addition, Update, Replacement, or Removal of Information. Please provide the Applicant information most recently provided to the FDA under the heading: Subsection A: Current Applicant Information. Please provide the proposed new Applicant information under the heading: Subsection B: Request for Change in Ownership. The addition of other new information (excluding Applicant name), or the update, replacement, or removal of previously provided information should be provided under the heading: Subsection C: Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact.

SECTION I – APPLICANT IDENTIFICATION

Subsection A. Current Applicant Information

(The organization (manufacturer/importer) seeking a marketing authorization for a new tobacco product)

Date of Submission

Name of Applicant *(Provide an organization's name)*

Organization Name:

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Applicant Address and Contact Information

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

Address 2 (Apt., Suite, Bldg., etc.)	City	
State, Province, or Territory	Country	ZIP or Postal Code

Current Contact Name *(Optional)*	First Name	M.I.	Last Name

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

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

Subsection B. Request for Change in Ownership

Proposed New Applicant Information

(Complete this section to update the Applicant Information to reflect information relating to the new owner of the SE Report)

Effective Date of Ownership Change

Name of Applicant *(Provide an organization's name)*

Organization Name:

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Applicant Address and Contact Information

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

Address 2 (Apt., Suite, Bldg., etc.)	City	
State, Province, or Territory	Country	ZIP or Postal Code

New Contact Name *(Optional)*	First Name	M.I.	Last Name
Prefix *(e.g., Mr., Ms., Dr.)*:	Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*	Position Title
Telephone *(Include Country Code if applicable)*	FAX	Email Address	

☐ Request to transfer all related submissions for the named product(s) to the new owner

☐ A notice is included stating that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant.

Transfer Requests

Tobacco Product Name *(Brand/Sub-brand)*

Related Submissions: List the FDA Submission Tracking Numbers (STNs) for all your previous submissions for the tobacco product.

Related Submission Type	Related Submission STN

Subsection C: Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact (Optional)

Addition, Update, Replacement, or Removal of Applicant Identification Information

If "Add" or "Replace" (not allowed for Applicant; use Subsection B.) is selected, provide all demographic information for the new party.
If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.
If "Remove" is selected, provide only the Company/Institution Name of the party to be removed.

Select type of Applicant Identification Information *(Select only one)*

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

Effective Date of Change

Select one *(If "Update" is selected, FDA will update the Applicant Identification address or contact information that was previously submitted)*

☐ Add ☐ Update ☐ Replace ☐ Remove

Person's Name *(Provide a person's name for Authorized Representative or U.S. Agent)*

First Name	M.I.	Last Name

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

Address and Contact Information

Primary Address (Street Address, P.O. Box; Provide the postal address for the Authorized Representative; optional for the Manufacturer or the U.S. Agent)

Street Address (Provide the physical location for the Manufacturer or the U.S. Agent; optional for the Authorized Representative)

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

State, Province, or Territory	Country	ZIP or Postal Code

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

Organization Name and Address Information *(Optional for the Authorized Representative or U.S. Agent)*

Organization Name

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

☐ Select for same address as New Applicant

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

State, Province, or Territory	Country	ZIP or Postal Code

Addition, Update, or Removal of Point of Contact

If "Add" is selected, provide all demographic information for the new party.
If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.
If "Remove" is selected, provide only the Company/Institution Name of the party to be removed.)

Select type of Point of Contact Information *(Select only one)*

☐ Applicant ☐ Manufacturer *(Other than Applicant)* ☐ Authorized Representative

☐ U.S. Agent ☐ Other, Regulatory ☐ Other, Technical

Select one: ☐ Add ☐ Update ☐ Remove

(If "Update" is selected, FDA will update the Applicant Identification address or contact information that was previously submitted)

Contact Name	First Name	M.I.	Last Name

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

Alternate Point of Contact Address and Contact Information

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

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

State, Province, or Territory	Country	ZIP or Postal Code

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

SECTION II – TOBACCO PRODUCT INFORMATION

Subsection A. Unique Identification of New and Predicate Tobacco Products

(This Subsection is optional and to be used only to change previously submitted information.
For a co-packaged tobacco product, complete Section II for each new tobacco product included within the co-package.
For grouped submissions, complete Section II for each tobacco product included in the bundle.)

Individual Tobacco Product *(Only the Previously Submitted New Tobacco Product Name is required. Provide other information only for updates to previously submitted information. Refer to Form 3965, Section VIII, Appendix B to select the appropriate Product Category and Subcategory.)*

New Tobacco Product Identification

(Complete for each individual new tobacco product. Refer to Form 3965, Section VII, Appendix B to select the appropriate Product Category and Subcategory.)

Select to Update or Remove New Tobacco Product ☐ Update ☐ Remove

Previously Submitted New Tobacco Product Name (Brand/Sub-Brand)

Updated New Tobacco Product Name (Brand/Sub-Brand) *(if applicable)*

Update New Tobacco Product Category and Subcategory or Update New Tobacco Product Subcategory

(Complete only if Category or Subcategory is different than previously submitted)

Previously Submitted New Tobacco Product:

Category: Subcategory:

Updated New Tobacco Product:

Category: Subcategory:

Predicate Tobacco Product Identification

(Complete for each individual predicate tobacco product. Refer to Form 3965, Section VII, Appendix B to select the appropriate Product Category and Subcategory)

Select to Update or Remove Predicate Tobacco Product ☐ Update ☐ Remove

Previously Submitted Predicate Tobacco Product Name (Brand/Sub-Brand)

Updated Predicate Tobacco Product Name (Brand/Sub-Brand) *(if applicable)*

Update Predicate Tobacco Product Category and Subcategory or Product Category and Component

(Complete only if Category or Subcategory is different than previously submitted)

Previously Submitted Predicate Tobacco Product:

Category: Subcategory:

Updated Predicate Tobacco Product:

Category: Subcategory:

Tobacco Product Properties Needed to Uniquely Identify the Product

(Update previously submitted Tobacco Product Properties by selecting Add, Update, or Remove and providing the Property Name. When updating properties provide both the previously submitted target value and the updated target value for either the new tobacco product or predicate tobacco product, or both.)

		New Tobacco Product Name:		Predicate Tobacco Product Name:	
Action *(Add, Update, Remove)*	Property Name	Previously Submitted Target Value	Updated Target Value	Previously Submitted Target Value	Updated Target Value

Subsection B: Tobacco Product Manufacturer Identification

New Tobacco Product Manufacturer *(Optional, provide if different from Applicant or Applicant is an Importer)*

The New Tobacco Product Manufacturer subsection is provided if the Applicant is not the new tobacco product manufacturer, or the Applicant is an importer of the new tobacco product. Provide information only to add new information, or update or remove previously submitted information.

☐ Select if Applicant is an Importer of the new tobacco product

Select to Add, Update, Replace, or Remove New Tobacco Product Manufacturer Information:

☐ Add ☐ Update ☐ Replace ☐ Remove

Current New Tobacco Product Name (Brand/Sub-Brand)
(Provide the previous name if no update, or provide the updated name.)

Organization Name

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)	City	
State, Province, or Territory	Country	ZIP or Postal Code

Predicate Tobacco Product Manufacturer *(if different from Applicant or Applicant is an Importer)*

The Predicate Tobacco Product Manufacturer subsection is provided if the Applicant is not the new tobacco product manufacturer, or the Applicant is an importer of the predicate tobacco product. Provide information only to add new information, or update, replace, or remove previously submitted information.

☐ Select if Applicant is an Importer of the Predicate Tobacco Product

Select to Add, Update, Replace, or Remove Predicate Tobacco Product Manufacturer Information:

☐ Add ☐ Update ☐ Replace ☐ Remove

Current Predicate Tobacco Product Name (Brand/Sub-Brand)
(Provide either the previously submitted name or the updated name provided on this amendment.)

Organization Name

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)	City	
State, Province, or Territory	Country	ZIP or Postal Code

Subsection C. Predicate Product Evidence

(Complete only if the predicate has not been previously reviewed by CTP.)

Evidence of Commercial Marketing as of February 15, 2007

Type of Evidence (e.g., Invoice)	Date of Evidence	Evidence Identifier (e.g., Invoice Number)
Commercial Information (e.g., UPC Code, Product Description, Item Number)		Product Quantity (as indicated by the evidence)

Commercially Marketed Business Address

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)	City	
State, Province, or Territory	Country	ZIP or Postal Code

Test Market Statement

I am signing in as: ☐ Applicant ☐ Authorized Representative ☐ U.S. Agent

First Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

I confirm that the predicate tobacco product associated with this Substantial Equivalence Submission for _____ was commercially marketed other than for test marketing in the United States as of February 15, 2007.

Signature	Date

SECTION III – SUBMISSION INFORMATION

Type of Submission *(Select only one)*

☐ Amendment *(If selected, provide Date of FDA Letter and Response Type)*	☐ General Correspondence *(If selected, provide Subject of Correspondence.)*
FDA Submission Tracking Number *(STN)* to be amended **Date of FDA Letter** *(If applicable mm/dd/yyyy)* **Amendment Response Type** *(Select one)*: Deficiency Letter Pre-Existing Tobacco Product Evidence *(Section II)* Unsolicited *(Describe in Submission Summary)* Correction to Product Identification Information *(Section II)* Change in Cross-referenced Content or Related Submissions *(Section III)* Request to Withdraw SE Report *Select to indicate if the withdrawal is due to a health or safety concern related to the tobacco product* Other *(Describe in Submission Summary)*	**Subject of Correspondence** *(Select all that apply)* Change to Applicant Address or Contact Information *(Section I)* Request for Change in Ownership *(Section I)* Change to Point of Contact *(Section I)* Other *(Describe in Submission Summary)*

Submission Summary *(Required if instructed to "Describe" by a previous selection.)*

Purpose of Application (Check only one)

☐ This SE Report Amendment is for a single new tobacco product

☐ This SE Report Amendment is for a group of SE Report Amendments containing multiple new tobacco products with similar modifications in comparison to one predicate tobacco product

Cross Reference to Tobacco Master Files

(As applicable, enter the STN, check the Attached Letter of Authorization box (if letter will be attached to printout or otherwise provided), and provide Master File information.)

Select to Add, Update, or Remove Tobacco Product Master File Information:

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name *(either previously submitted or updated name)*

☐ Select if this update to Tobacco Master File(s) is relevant to all amended products in this submission

STN	☐ Attached Letter of Authorization

Information and Selections to be referenced from Master File

Cross-referenced Content
(Optional, use this subsection to add new cross-referenced content, or update or remove previously submitted information)

Select to Add, Update, or Remove Cross-referenced Content:

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name *(either previously submitted or updated name)*

☐ Select if this update to Cross-referenced Content is relevant to all amended products in this submission

Cross-referenced Submission Type	Cross-referenced Submission STN	Document Filename

Related Submissions
List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., SE, PTP, TPMF) where applicable

Select to Add, Update, or Remove Related Submissions:

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name *(either previously submitted or updated name)*

☐ Select if this Related Submission is relevant to all grouped products

Related Submission Type	Related Submission STN

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

Select to Add, Update, or Remove Formal Meetings Held with FDA:

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name *(either previously submitted or updated name)*

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the SE Report Amendment, according to their respective subject area.
(Refer to Form 3965, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative
(List the categories of Administrative content provided by this Amendment)

Product Information
(List the categories of Product Information content provided by this Amendment)

Health and Research
(List the categories of Health and Research content provided by this Amendment)

Comparisons
(List the categories of Comparisons content provided by this Amendment)

Other Content *(Describe the other content provided by this Amendment)*

Environmental Considerations *(Select only one)*

☐ Environmental Assessment ☐ Claim for Categorical Exclusion

SECTION V - MANUFACTURING/PACKAGING SITES RELATING TO A SUBMISSION

(This section is optional.
If "Add" is selected, provide all demographic information for the new site.
If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.
If "Remove" is selected, provide only the Company/Institution Name of the site to be removed.)

Select to Add, Update, or Remove Manufacturing/Packaging Site

☐ Add ☐ Update ☐ Remove

Company/Institution Name

Specify Type of Manufacturing/Packaging Site

☐ Manufacturer ☐ Contract Manufacturer ☐ Repacker/Relabeler

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Division Name (if applicable)

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)	City	
State, Province, or Territory	Country	ZIP or Postal Code
Telephone *(Include Country Code if applicable)*	FAX	Email Address

Contact Name	First Name	M.I.	Last Name

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

SECTION VI – CERTIFICATION STATEMENT

I am signing as a/an: ☐ Applicant ☐ Authorized Representative ☐ U.S. Agent

First Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the Applicant's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

Signature	Date

INSTRUCTIONS

Section I – Applicant Identification

Subsection A – Current Applicant Information

- Complete Applicant name and address information as previously submitted, and optionally provide contact name, telephone, and email address. (Changes to the current Applicant information should be made only in Subsection C.)

Subsection B – Request for Change in Ownership

- Provide the effective date of the change in ownership.
- Complete proposed Applicant name and address information, and optionally provide contact name, telephone, and email address.
- Indicate if a notice is included stating that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. (List the notice in Section IV under Administrative contents.)
- Indicate if you are transferring all related submissions related to a brand or brands.
- If so, provide the tobacco product names and corresponding STNs subject to the change in ownership.

Subsection C – Addition, Update, or Removal of Applicant Identification Information or Point of Contact

- Optionally select the type of Applicant information, e.g., Applicant, U.S. Agent, etc., being provided.
- Optionally select to add, update, or remove Applicant information. To update or remove information, the Person's Name or Organization name must match previously submitted information.
- Optionally select the type of Point of Contact information, e.g., Applicant, U.S. Agent, etc., being provided.
- Optionally select to add, update, or remove Point of Contact information. To update or remove information for a Point of Contact, the Person's Name must match previously submitted information.

Section II – Tobacco Product Identification

Subsection A – Unique Identification of Tobacco Products

- For an individual tobacco product, provide the new and predicate tobacco products' names. Product category, subcategory, and product properties should be provided only if they are changing.
- For a co-packaged tobacco product, provide the new and predicate tobacco products' names for all products in the co-packaged tobacco product by adding Section II for each products. Product category, subcategory, and product properties should be provided only if they are changing.
- Add an individual tobacco product by selecting "Add Section II" on the form.

Subsection B – Tobacco Product Manufacturer Information

- Provide tobacco product manufacturer information only to add new information, or update or remove previously submitted information. As explained in the SE Report submission form (3965), manufacturer information need only be provided if the manufacturer is different from the Applicant.
- Optionally select to Add, Update, or Remove information for either the new tobacco product manufacturer or the predicate tobacco product manufacturer.

Subsection C – Predicate Product Evidence

(Complete this section if relying on a pre-existing tobacco product as your predicate product. If necessary, please update your application with additional evidence to support its pre-existing status.)

- Type of Evidence: Provide brief description of what is submitted, e.g., invoice, bill of lading, etc.
- Date of Evidence: Provide the date on the evidence.
- Evidence Identifier: Provide an identifying number or code for the evidence type, e.g., invoice number.
- Commercial Information: Provide UPC Code, SKU number, or other product identifier, if applicable.
- Tobacco Product Quantity: Provide the quantity of the product as identified in the evidence.
- Business Address where product was commercially marketed: Provide the address of the establishment subject to the evidence provided, e.g., the location of the establishment that the product was commercially sold on February 15, 2007.

Section III – Submission Information

- Indicate whether the submission is an Amendment or General Correspondence.
- Provide the FDA STN being amended. The Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission should be used to update only one STN.
- If an amendment is responding to an FDA letter, provide the date of the letter and the type of FDA letter, e.g., Advice/Information Request, or type of response, e.g., Unsolicited. If “Unsolicited” or “Other”, describe the purpose of the submission in the Submission Summary.
- If the submission is General Correspondence, select the subject of the correspondence and provide the appropriate information in the Section indicated. If “Other”, describe the subject of the correspondence in the Submission Summary.
- Indicate whether the submission is for a single individual tobacco product or for a group of tobacco products previously submitted as a grouped SE Report submission.
- Optionally add, update, or remove cross-referenced content, including Tobacco Product Master Files, by referencing documents provided in related submissions.
- Optionally add, update, or remove related submissions, (e.g., SE, PTP, and TPMF).
- Optionally add, update, or remove formal meetings held with FDA pertaining to the new tobacco product.

Section IV – Amendment and General Correspondence Contents

- Select the categories of document submitted from among Administrative, Product Information, Health and Research, Comparisons between the new and predicate products, or Environmental Considerations. For each category, list the subcategories that describe the submission contents.

Section V – Manufacturing/Packaging Site Relating to a Submission

- Optionally select to add, update, or remove Manufacturing/Packaging Site information. To update or remove
  information for a Manufacturing/Packaging Site, the “Company/Institution Name” must match previously submitted information.
- If "Add" is selected, provide all demographic information for the new site. If "Update" is selected, provide only “Company/ Institution Name” and the information which will replace previously submitted information. If "Remove" is selected, provide only the "Company/ Institution Name" of the site to be removed.

Section VI – Certification Statement

- Select if the signer is acting as an Authorized Representative or U.S. Agent.
- Insert the name of the signer, and sign and date the form where indicated.

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

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

The burden time for this collection of information is estimated to average 10 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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