

TOBACCO SUBSTANTIAL EQUIVALENCE REPORT SUBMISSION

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 (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.”

Section 910(a)(2) of the FD&C Act states that premarket review is required for new tobacco products. There are three pathways to receive marketing authorization. Substantial equivalence is one of the three pathways.

Section 910(a)(3) of the FD&C Act states that “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 timeframe and basis for submission of a substantial equivalence Report (SE Report).

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TOBACCO SUBSTANTIAL EQUIVALENCE REPORT SUBMISSION

SECTION I – APPLICANT IDENTIFICATION

Type of Manufacturer (Check appropriate box)

Manufacture, fabricate, assemble, process, or label a tobacco product (see section 900(20) of the FD&C Act)

Import a finished tobacco product for sale or distribution in the U.S.

Manufacturer Name

FDA Establishment Identifier (FEI)

D&B DUNS Number of Headquarters

Manufacturer Street Address
(Physical location)

Building Number and Street

Designer note: This form will be made as a "508 compliant" Adobe LiveCycle PDF with fillable entry fields after FDA (along with OMB, if applicable) gives final approval to this "layout design" version.

Room, Suite, Office, etc. (If applicable)

City

State, Province, or Territory

Country

Postal Code

Authorized Representative

(Responsible official authorized to represent the applicant)

Prefix (e.g., Mr., Ms., Dr.):

First Name

M.I.

Last Name

Suffix (e.g., Jr., III)

Professional Suffix (e.g., MD, Ph.D.)

Position Title

Email Address

Telephone (Include Country Code if applicable)

FAX

Authorized Representative Mailing Street Address

Building Number and Street

Room, Suite, Office, etc. (If applicable)

City

State, Province, or Territory

Country

Postal Code

U.S. Agent

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

Prefix (e.g., Mr., Ms., Dr.):

First Name

M.I.

Last Name

Suffix (e.g., Jr., III)

Professional Suffix (e.g., MD, Ph.D.)

Position Title

Email Address

Telephone (Include Country Code if applicable)	FAX
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U.S. Agent Mailing Street Address	Building Number and Street
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Room, Suite, Office, etc. (If applicable)	City
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State, Province, or Territory	Country	Postal Code
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Alternate Point of Contact
(Secondary point of contact for applicant)

Prefix (e.g., Mr., Ms., Dr.):

First Name	M.I.	Last Name	Suffix (e.g., Jr., III)
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Professional Suffix (e.g., MD, Ph.D.)	Position Title	Email Address
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Telephone (Include Country Code if applicable)	FAX
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SECTION II – SUBMISSION INFORMATION

Proposed modification(s) to the New Tobacco Product (as compared to the predicate tobacco product) (Check all that apply)

- Tobacco Blend
- Design
- Material
- Container Closure System
- Heating Source
- Product Quantity
- Ingredients (Specify): _____
- Other (Specify): _____

Submission Summary (As described in 21 C.F.R. 1107.18(d), please summarize the submission below)

Purpose of Application (Check only one)

- This SE Report is for an individual new tobacco product.
- This SE Report is for a bundled submission containing multiple new tobacco products with similar modifications in comparison to one predicate tobacco product.

References to Other CorrespondenceRelated Submission Tracking Numbers (STNs) *(List below)*

Cross Reference to Tobacco Product 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.)*

STN: _____

 Attached Letter of AuthorizationInformation and Sections to be referenced from Master File *(Enter below)*

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

	<i>STN</i>	<i>Meeting Held Date</i>	
1st Meeting			PROOF
2nd Meeting			
3rd Meeting			
4th Meeting			
5th Meeting			
6th Meeting			
7th Meeting			
8th Meeting			
9th Meeting			
10th Meeting			

SECTION III – NEW TOBACCO PRODUCT INFORMATION

Refer to Section VIII, Appendix B, and select the appropriate category and sub-category.

For a bundled or co-packaged submission, complete all parts of this Section III for each individual new tobacco product.

For every comparison being made, the category and sub-category of both the new and predicate tobacco product should be the same.

Select either or both, if applicable.

New tobacco product is a component

New tobacco product is co-packaged

Select all that apply below. Complete for each individual new tobacco product.

New Tobacco Product Name (Brand/Sub-Brand)

Product Category/Sub-Category

Cigarette

- Combusted, Filtered
- Combusted, Non-Filtered
- Non-combusted
- Combusted, Other (Specify below)

Cigar

- Leaf-Wrapped
- Filtered, Sheet-Wrapped
- Non-Filtered, Sheet-Wrapped
- Cigar Tobacco Filler
- Cigar, Other (Specify below)

Electronic Nicotine Delivery System (ENDS)

- Open E-Liquid
- Closed E-Liquid
- Open E-Cigarette
- Closed E-Cigarette
- ENDS, Other (Specify below)

Pipe Tobacco Products

- Pipe
- Pipe Tobacco Filler
- Pipe, Other (Specify below)

Roll-Your-Own Tobacco Products

- Roll-Your-Own Tobacco Filler
- Rolling Paper
- Filtered Cigarette Tube
- Non-Filtered Cigarette Tube
- Filter
- Paper Tip
- Roll-Your-Own, Other (Specify below)

Smokeless Tobacco Products

- Loose Moist Snuff
- Portioned Moist Snuff
- Loose Snus
- Portioned Snus
- Loose Dry Snuff
- Dissolvable
- Loose Chewing
- Portioned Chewing
- Smokeless, Other (Specify below)

Waterpipe Tobacco Products

- Waterpipe
- Waterpipe Tobacco Filler
- Waterpipe Heat Source
- Waterpipe, Other (Specify below)

SECTION IV – PREDICATE TOBACCO PRODUCT INFORMATION

Refer to Section VIII, Appendix B, and select the appropriate category and sub-category.

The category and sub-category should be the same as each individual new tobacco product.

Select either or both, if applicable.

- Predicate tobacco product is a component Predicate tobacco product is co-packaged

Select all that apply below. Complete for each individual predicate tobacco product.

Predicate Tobacco Product Name (Brand/Sub-Brand)

Predicate Category/Sub-Category

Cigarette

- Combusted, Filtered
 - Combusted, Non-Filtered
 - Non-combusted
 - Combusted, Other (Specify below)
- _____

Cigar

- Leaf-Wrapped
 - Filtered, Sheet-Wrapped
 - Non-Filtered, Sheet-Wrapped
 - Cigar Tobacco Filler
 - Cigar, Other (Specify below)
- _____

Electronic Nicotine Delivery System (ENDS)

- Open E-Liquid
 - Closed E-Liquid
 - Open E-Cigarette
 - Closed E-Cigarette
 - ENDS, Other (Specify below)
- _____

Pipe Tobacco Products

- Pipe
 - Pipe Tobacco Filler
 - Pipe, Other (Specify below)
- _____

Roll-Your-Own Tobacco Products

- Roll-Your-Own Tobacco Filler
 - Rolling Paper
 - Filtered Cigarette Tube
 - Non-Filtered Cigarette Tube
 - Filter
 - Paper Tip
 - Roll-Your-Own, Other (Specify below)
- _____

Smokeless Tobacco Products

- Loose Moist Snuff
 - Portioned Moist Snuff
 - Loose Snus
 - Portioned Snus
 - Loose Dry Snuff
 - Dissolvable
 - Loose Chewing
 - Portioned Chewing
 - Smokeless, Other (Specify below)
- _____

Waterpipe Tobacco Products

- Waterpipe
 - Waterpipe Tobacco Filler
 - Waterpipe Heat Source
 - Waterpipe, Other (Specify below)
- _____

Complete the subsection below for the predicate tobacco product if the Applicant is not the predicate tobacco product manufacturer or the Applicant is an Importer of that individual predicate tobacco product.

Predicate Tobacco Product Manufacturer
(If other than Applicant or Applicant is an Importer)

Predicate Name

Manufacturer Name

FDA Establishment Identifier (FEI)

D&B DUNS Number of Headquarters

Street Address

Building Number and Street

Room, Suite, Office, etc. (If applicable)

City

State, Province, or Territory

Country

Postal Code

Predicate Tobacco Product Basis

Check the statement below that applies to the predicate tobacco product, and then complete all necessary information for that statement.

- The predicate tobacco product identified above was submitted for GF review independently of this SE Report and was determined to be a grandfathered (GF) product.

Name of Product

GF/SE STN

Date of FDA's GF Determination

- The predicate tobacco product was previously found to be substantially equivalent.

Name of Product

GF/SE STN

Date of FDA's GF Determination

- The predicate tobacco product was not previously submitted for GF review and was not previously found to be substantially equivalent, but we believe it to be a grandfathered product.

Complete A and B below and attach all documentation, which must demonstrate the predicate tobacco product identified above was commercially marketed other than for test marketing in the United States as of February 15, 2007. Subsection A should be completed for each attached document.

A. 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, SKU Number)	
Commercially Marketed Business Address		Building Number and Street	
Room, Suite, Office, etc. (If applicable)		City	
State, Province, or Territory	Country		Postal Code

B. Statement of Affirmation	
I _____, confirm that the predicate tobacco product <i>(Name of responsible official)</i>	
_____ was commercially marketed (other than <i>(Name of predicate tobacco product)</i>	
exclusively for test marketing) in the United States as of February 15, 2007.	
Signature	Date

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SECTION V – UNIQUE IDENTIFICATION OF NEW AND PREDICATE TOBACCO PRODUCTS

Each individual new tobacco product must be in comparison to one predicate tobacco product. Refer to the table below and to section VIII, Appendix A, to determine the appropriate table needed to document all new tobacco products and predicate tobacco products listed within this application. Fill in the table below and/or attach additional tables to this section as needed.

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

Tobacco Product – Component or Co-Packaged? (If applicable, select the appropriate box(es))

- Tobacco product is a component
 Tobacco product is co-packaged

In the following table, please enter the name of both the new and predicate tobacco products, and list the properties of each product below its name. Twenty-six rows for properties are provided, as needed, for each name.

Product Identification				
	New Tobacco Product		Predicate Tobacco Product	
Name:				
Properties	1		1	
	2		2	
	3		3	
	4	Designer note: Currently plan to have 26 separate entry	4	
	5	fields within each column (one user line of text per	5	
	6	field).	6	
	7		7	
	8		8	
	9		9	
	10		10	
	11		11	
	12		12	
	13		13	
	14		14	
	15		15	
	16		16	
	17		17	
	18		18	
	19		19	
	20		20	
	21		21	
	22		22	
	23		23	
	24		24	
	25		25	
	26		26	

SECTION VI – CERTIFICATION STATEMENTS

For the following section, state the name of the responsible official, the name of the company being represented within this application, the individual new tobacco product(s), and the individual predicate tobacco product(s). Complete the information for all applications.

Name of authorized representative (In this section, referred to as “the authorized representative”)

Name company being represented (In this section, referred to as “the company”)

Name of new tobacco product(s) (In this section, referred to as “new tobacco product”)

Name of predicate tobacco product(s) (In this section, referred to as “predicate tobacco product”)

Complete the certification statement below.

I (name of responsible official) _____, on behalf of (applicant) _____, hereby certify that (applicant) _____, will maintain all records to substantiate the accuracy of this SE Report for the period of time required in § 1107.58 and ensure that such records remain readily available to the 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 to the Government of the United States is subject to criminal penalties.

Complete the statement below if choosing to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco products.

I (name of responsible official) _____, on behalf of (name of company) _____, certify that (new tobacco product name) _____, 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 (new tobacco product name) _____ 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 § 1107.19 that substantiate the accuracy of this statement for the period of time required in § 1107.58, and ensure that such records remain readily available to FDA upon request.

In accordance with proposed 1107.18, the following information is provided within the SE Report. Check all applicable statements to which you attest, and then sign the statement below

- General Information (1107.18(c))
- Summary (1107.18(d)(1-3))
- New tobacco product description (1107.18(e))
- Predicate tobacco product description (1107.18(f))
- Comparison information (1107.18(g))
- Comparative testing information (1107.18(h))
- Statement of compliance with applicable product standards (1107.18(i))
- Health information summary or statement that health information is available upon request (1107.18(j))
- Compliance with 21 CFR part 25 (1107.18(k))
- Certification (As set out in Section IV of this form, and includes certifications on record maintenance and availability, truthfulness, and as applicable, that certain characteristics are identical.) (1107.18(l)(1) and/or (2))

By signing below, I, _____, certify that statements selected above are true.

Signature

Date

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SECTION VII – SUBMISSION INFORMATION AND CONTENTS

Ensure all appropriate documents are included in this SE Report. Check all that apply

Administrative

- Cover Letter
- Table of Contents
- Submission Summary
- Basis of SE Determination
- Unique Identification of new tobacco product(s) and predicate tobacco product(s)
- Statements of Certification (Section VI)

Product Information

- List of Ingredients
- Information on Manufacturing Process

Health and Research *(Select only one if this applies)*

- Health Information Summary
OR
- Health Information Statement

Comparisons *(New vs. Predicate Tobacco Product)*

- Product Design
- Heating Sources

Comparisons *(Continued)*

- Composition
 - Materials
 - Ingredients, Tobacco
 - Ingredients, non-Tobacco
- Other features
 - HPHCs
 - Other *(Specify below)*

- Stability
- Applicant's basis for SE
- Comparison to grandfathered product *(Check only if predicate product was previously found SE.)*

Environmental Considerations *(Select only one if this applies)*

- Environmental Assessment
OR
- Claim for Categorical Exclusion

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SECTION VIII – APPENDICES

Appendix A: New Tobacco Product and Predicate Tobacco Product Details

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

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

Unique Product Identification		
Properties <i>(Inserted on form)</i>	New Tobacco Product <i>Name: Product A</i>	Predicate Tobacco Product <i>Name: Predicate A</i>
Package Type	Box	Box
Product Quantity	20 Cigarettes per box	20 Cigarettes per box
Diameter	100 mm	92 mm
Length	6 mm	6 mm
Ventilation	None	None
Characterizing Flavor	None	None
Additional Properties	Red color box	Blue color box

Below is an example of multiple new tobacco products in comparison to a single predicate tobacco product.

Unique Product Identification				
Properties <i>(Inserted on form)</i>	New Product 1 <i>Name: Product A</i>	New Product 2 <i>Name: Product B</i>	New Product 3 <i>Name: Product C</i>	Predicate <i>Name: Predicate A</i>
	<i>STN: N/A</i>	<i>STN: N/A</i>	<i>STN: N/A</i>	<i>STN: GF1234567</i>
Package Type	Box	Box	Box	Box
Product Quantity	20 Cigarettes per box	20 Cigarettes per box	20 Cigarettes per box	20 Cigarettes per box
Length	100 mm	96 mm	94 mm	92 mm
Diameter	6 mm	4 mm	6 mm	6 mm
Ventilation	None	None	None	None
Characterizing Flavor	None	None	None	None
Additional Properties	Red color box	Purple color box	Red color box	Blue color box

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

Name of Co-Package: Variety Pack A/B		
Unique Product Identification		
<i>Co-Packaged Categories and Unique Identification Properties</i>	<i>New Tobacco Product(s)</i>	<i>Predicate Tobacco Product(s)</i>
<i>Category: Roll-Your-Own Sub-Category: Roll-Your-Own Tobacco Filler</i>	<i>Name: Product A</i>	<i>Name: Predicate A</i> <hr/> <i>Related STN: GF1234567</i>
Package Type	Bag	Bag
Product Quantity	100 g	100 g
Characterizing Flavor	None	None
Additional Properties	Re-sealable Bag	Blue Bag
<i>Category: Roll-Your-Own Sub-Category: Roll-Your-Own Rolling Paper</i>	<i>Name: Product B</i>	<i>Name: Predicate B</i> <hr/> <i>Related STN: GF7654321</i>
Package Type	Booklet	Booklet
Product Quantity	100 sheets	85 sheets
Length	100 mm	98 mm
Width	56 mm	52 mm
Characterizing Flavor	None	None
Additional Properties	Black Box	Black Box

Appendix B: Unique Identification of Category and Sub-Categories and Properties

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

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

Cigarette Tobacco Products	
<i>Properties</i>	<i>Sub-Categories</i>
	<i>All Cigarettes</i>
Package Type	X
Product Quantity	X
Diameter	X
Length	X
Ventilation	X <i>(except combusted, non-filtered)</i>
Characterizing Flavor	X
Additional Properties	X
Note: For non-combusted cigarettes, include the source of energy.	

Roll-Your-Own Tobacco Products							
<i>Properties</i>	<i>Sub-Categories</i>						
	<i>Tobacco Filler</i>	<i>Rolling Paper</i>	<i>Filtered Cigarette Tube</i>	<i>Non-Filtered Cigarette Tube</i>	<i>Filter</i>	<i>Paper Tip</i>	<i>Other</i>
Package Type	X	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X	X
Diameter			X	X	X		
Length		X	X	X	X	X	
Ventilation			X		X		
Width		X				X	
Characterizing Flavor	X	X	X	X	X	X	X
Additional Properties	X	X	X	X	X	X	X

Cigar						
Properties	Sub-Categories					
	<i>Component</i>	<i>Filtered Sheet-Wrapped</i>	<i>Unfiltered Sheet-Wrapped</i>	<i>Leaf-Wrapped</i>	<i>Tobacco Filler</i>	<i>Other</i>
Package Type	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X
Length		X	X	X		
Diameter		X	X	X		
Ventilation		X				
Tobacco Cut Size					X	
Wrapper Material				X		
Tip			X			
Characterizing Flavor	X	X	X	X	X	X
Additional Properties	X	X	X	X	X	X

Smokeless Tobacco Products									
Properties	Sub-Categories								
	<i>Loose Moist Snuff</i>	<i>Portioned Moist Snuff</i>	<i>Loose Snus</i>	<i>Portioned Snus</i>	<i>Loose Dry Snuff</i>	<i>Dissolvable</i>	<i>Loose Chewing</i>	<i>Portioned Chewing</i>	<i>Other</i>
Package Type	X	X	X	X	X	X	X	X	X
Product Quantity	X	X	X	X	X	X	X	X	X
Portion Count		X		X		X		X	
Tobacco Cut Size	X	X	X	X	X	X	X		
Portion Length		X		X		X		X	
Portion Width		X		X		X		X	
Portion Mass		X		X		X		X	
Portion Thickness		X		X		X		X	
Characterizing Flavor	X	X	X	X	X	X	X	X	X
Additional Properties	X	X	X	X	X	X	X	X	X

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

Pipe Tobacco Products				
Properties	Sub-Categories			
	<i>Component</i>	<i>Pipe</i>	<i>Tobacco Filler</i>	<i>Other</i>
Package Type	X	X	X	X
Product Quantity	X	X	X	X
Length		X		
Diameter		X		
Characterizing Flavor	X	X	X	X
Additional Properties	X	X	X	X

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

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

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