

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.” (Pre-Existing Tobacco Product) (PTP)

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).

This page is deliberately blank.

**TOBACCO SUBSTANTIAL EQUIVALENCE
REPORT SUBMISSION**

SECTION I – APPLICANT IDENTIFICATION

Applicant Information

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

Type of Applicant (Check appropriate box)

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

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

Date of Submission

Name of Applicant

(Provide an organization's name)

Organization Name

Company Headquarters' FDA-assigned Facility Establishment Identifier (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

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

Telephone (Include Country Code if applicable)

FAX

Email Address

Authorized Representative Information

(Responsible official authorized to represent the applicant)

Name of Authorized Representative
(Provide a person's 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

Authorized Representative 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	

Organization Name and Address Information (Optional)	Organization Name		
Primary Address (Street Address, P.O. Box)		<input type="checkbox"/> Select for same address as Authorized Representative	
Address 2 (Apt., Suite, Bldg., etc.)		City	
State, Province, or Territory	Country		ZIP or Postal Code

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

Name of U.S. Agent (Provide a person's 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

U.S. Agent Address and Contact Information		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		

Organization Name and Address Information (Optional)	Organization Name			
Primary Address (Street Address, P.O. Box)		<input type="checkbox"/> Select for same address as U.S. Agent		
Address 2 (Apt., Suite, Bldg., etc.)		City		
State, Province, or Territory	Country		ZIP or Postal Code	

Alternate Point of Contact

(Optional, select only one for each Alternate Point of Contact. Provide one or more persons to contact as an Alternate to the Contacts provided elsewhere in this form.)

Applicant Manufacturer (Other than Applicant)		Authorized Representative U.S. Agent		Other, Regulatory Other, Technical	
Prefix (e.g., Mr., Ms., Dr.)	First Name	M.I.	Last Name		
Professional Suffix (e.g., MD, Ph.D.)	Generational Suffix (e.g., Jr., III)		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

Unique Identification of New and Predicate Tobacco Products

You must uniquely identify both the new tobacco product(s) and the predicate tobacco product(s). Refer to Section VII, Appendix A, to determine the appropriate table needed to document new tobacco products and predicate tobacco products included in this application.

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

New Tobacco Product Identification

Complete for each individual new tobacco product. Refer to Section VII, Appendix B, and select the appropriate category and subcategory. For bundled submissions or co-packaged products, select all that apply.

- Check this box if your product is co-packaged, meaning multiple components are contained in the same container closure system (e.g., a tin that contains both loose tobacco filler and rolling papers together).

Fill out Section II for all components of your co-packaged product.

New Tobacco Product Name (Brand/Sub-Brand)

Product Category and Subcategory or Product Category and Component

Cigarettes

- Filtered
 Non-Filtered
 Other (Specify below)
- _____

Cigars

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

Electronic Nicotine Delivery Systems (Vapes)

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

Pipe Tobacco Products

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

Heated Tobacco Products (HTP)

- Closed HTP
 Open HTP
 HTP Consumable
 HTP Component
 HTP, 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

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

Waterpipe Tobacco Products

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

Other (Specify below)

- Other (Specify below)
- _____

Predicate Tobacco Product Identification

Complete for each individual predicate tobacco product. Refer to Section VII, Appendix B, and select the appropriate category and subcategory. For bundled submissions or co-packaged products, select all that apply.

Predicate Tobacco Product Name (Brand/Sub-Brand)

Predicate Category and Subcategory or Predicate Category and Component

Cigarettes

- Filtered
 - Non-Filtered
 - Other (Specify below)
- _____

Cigars

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

Electronic Nicotine Delivery Systems (Vapes)

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

Pipe Tobacco Products

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

Heated Tobacco Products (HTP)

- Closed HTP
 - Open HTP
 - HTP Consumable
 - HTP Component
 - HTP, 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

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

Waterpipe Tobacco Products

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

Other (Specify below)

- Other (Specify below)
- _____

Tobacco Product Manufacturer Identification

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

Select if Applicant is an Importer

New Tobacco Product Manufacturer (If different from Applicant or Applicant is an Importer)

New Tobacco Product Name

Organization Name

Company Headquarters FDA-assigned
Facility Establishment Identifier (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

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 different from Applicant or Applicant is an Importer)

Predicate Tobacco Product Name

Organization Name

Company Headquarters' FDA-assigned
Facility Establishment Identifier (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

Basis for Predicate Tobacco Product Eligibility

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 PTP review independently of this SE Report and was determined to be a pre-existing tobacco product (PTP) and may be eligible to serve as a predicate.

Name of Product	
PTP STN	Date of FDA's PTP Determination

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

Name of Product	
SE STN	Date of FDA's previous SE Determination

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

Complete section B below if the first check box above is selected. Complete A and B below if the third check box above is selected and attach all documentation needed to demonstrate that the predicate tobacco product identified above was commercially marketed other than for test marketing in the United States as of February 15, 2007. Neither section A or B is required if you are relying on a predicate product that was previously found to be substantially equivalent (second check box).

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

B. Statement of Affirmation

I _____, confirm that the predicate tobacco product
(Name of responsible official)
_____, was commercially marketed (other than
(Name of predicate tobacco product)
exclusively for test marketing) in the United States as of February 15, 2007.

Signature	Date
-----------	------

SECTION III – SUBMISSION INFORMATION

For a co-packaged tobacco product, complete Section III for each new tobacco product included within the co-package.

For grouped submissions, complete Section III for each tobacco product included in the bundle.

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 is a group of SE Reports containing multiple new tobacco products with similar modifications in comparison to one predicate tobacco product.

Type of Application (Check only one)

Same Characteristics report

Different Characteristics report

Cross-Referenced Content: 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 Authorization

Information and Sections to be referenced from Master File (Enter below)

Identify Cross-referenced Submission Type as one of the following: SE, PTP, or Tobacco Product Master File (TPMF)

New Tobacco Product Name (Provide product name if this Cross-referenced Content is relevant to a specific product)

Select if this Cross-referenced Content is relevant to all grouped products

Cross-referenced Submission Type	Cross-referenced Submission STN
----------------------------------	---------------------------------

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

New Tobacco Product Name (Provide product name if this Related Submission is relevant to a specific product)

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 number and meeting held date.*)

New Tobacco Product Name (Provide product name if meeting is relevant to a specific product)	Select if this Meeting is relevant to all grouped products	Submission STN	Meeting Held Date
	<input type="checkbox"/>		

SECTION IV – APPLICATION 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)*

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 pre-existing tobacco product *(Check only if predicate product was previously found SE.)*

Environmental Considerations *(Select only one)*

Environmental Assessment
OR
Claim for Categorical Exclusion

SECTION V - MANUFACTURING / PACKAGING SITES RELATING TO A SUBMISSION

(Add additional Manufacturing/Packaging sites as needed)

Company/Institution Name

Manufacturer		Contract Manufacturer		Repacker/Relabeler	
Company Headquarters' FDA-assigned Facility Establishment Identifier (FEI) Number				Company Headquarters' D&B DUNS® Number	
Division Name (If applicable)				Primary Address (Street Address, P.O. Box)	
City	State, Province or Territory	ZIP or Postal Code	Country		
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 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 of 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 C.F.R. 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

SECTION VII – 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 II.

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		
<i>Properties</i> <i>(Inserted on form)</i>	<i>New Tobacco Product</i> <i>Name: Product A</i>	<i>Predicate Tobacco Product</i> <i>Name: Predicate A</i>
Package Type	Box	Box
Package 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	N/A	N/A

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

Unique Product Identification				
<i>Properties</i> <i>(Inserted on form)</i>	<i>New Product 1</i> <i>Name: Product A</i> <i>STN: N/A</i>	<i>New Product 2</i> <i>Name: Product B</i> <i>STN: N/A</i>	<i>New Product 3</i> <i>Name: Product C</i> <i>STN: N/A</i>	<i>Predicate</i> <i>Name: Predicate A</i> <i>STN: As Assigned by FDA</i>
Package Type	Box	Box	Box	Box
Package Quantity	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	N/A	N/A	N/A	N/A

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>Category: Roll-Your-Own Subcategory: Roll-Your-Own Tobacco Filler</i>	<i>Name: Component A</i>	<i>Name: Predicate A</i>
Package Type	Bag	Bag
Package Quantity	100 g	150 g
Characterizing Flavor	None	None
Additional Properties	Re-sealable Bag	Re-sealable Bag
<i>Category: Roll-Your-Own Subcategory: Roll-Your-Own Rolling Paper</i>	<i>Name: Component B</i>	<i>Name: Predicate B</i>
Package Type	Booklet	Booklet
Package Quantity	100 sheets	100 sheets
Length	100 mm	85 mm
Width	56 mm	56 mm
Characterizing Flavor	None	None
Additional Properties	N/A	N/A

Appendix B: Properties Needed to Uniquely Identify the Tobacco Product, by Category and Subcategory

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

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

Cigarette Tobacco Products	
Properties	Subcategories
	All Cigarettes
Package Type	X
Product Quantity	X
Diameter	X
Length	X
Ventilation	X (except non-filtered)
Characterizing Flavor	X
Additional Properties (if applicable)	X

Roll-Your-Own Tobacco Products							
Properties	Subcategories						
	<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				
Width		X				X	
Characterizing Flavor	X	X	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X	X	X

Cigar						
Properties	Subcategories					
	<i>Component</i>	<i>Filtered Sheet-Wrapped</i>	<i>Unfiltered Sheet-Wrapped</i>	<i>Unfiltered 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				
Wrapper Material	-	-	-	X	-	-
Tip			X			
Characterizing Flavor	X	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X	X

Smokeless Tobacco Products									
Properties	Subcategories								
	<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	
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 (if applicable)	X	X	X	X	X	X	X	X	X

Electronic Nicotine Delivery Systems (Vapes)

Properties	Subcategories					
	Component	Open E-Liquid	Closed E-Liquid	Open E-Cigarette	Closed E-Cigarette	Other
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 (if applicable)	X	X	X	X	X	X

Heated Tobacco Products (HTP)

Properties	Subcategories				
	Component	Closed HTP	Open HTP	Consumable	Other
Package Type	X	X	X	X	X
Product Quantity	X	X	X	X	X
Length		X	X	X	
Diameter	-	X	X	X	-
Ventilation				X	
Wattage	-	X	X	-	-
Battery Capacity		X	X		
Characterizing Flavor	X	X	X	X	X
Additional Properties (if applicable)	X	X	X	X	X

Pipe Tobacco Products				
Properties	Subcategories			
	<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
Tobacco Cut Style			X	
Length	-	X	-	-
Diameter		X		
Characterizing Flavor	X	X	X	X
Additional Properties (if applicable)	X	X	X	X

Waterpipe Tobacco Products					
Properties	Subcategories				
	<i>Component</i>	<i>Waterpipe</i>	<i>Heat Source</i>	<i>Tobacco Filler</i>	<i>Other</i>
Package Type	X	X	X	X	X
Product Quantity	X	X	X	X	X
Height		X			
Width	-	X	-	-	-
Diameter		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 (if applicable)	X	X	X	X	X

Other Products	
Properties	Subcategory
	Other
Package Type	X
Product Quantity	X
Characterizing Flavor	X
Additional Properties (if applicable)	X

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 45 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
PRStaff@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.”