DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# TOBACCO SUBSTANTIAL EQUIVALENCE REPORT 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 (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).

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## 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) | ☐ 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) | ☐ 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 ☐ Authorized Representative ☐ Other, Regulatory

☐ Manufacturer (Other than Applicant) ☐ U.S. Agent ☐ 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 Properties*

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

| | New Tobacco Product | Predicate Tobacco Product |
|---|---|---|
| Name: | | |
| Property | Target Value | Target Value |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |

## 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 |
|---|---|---|---|
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |
| | ☐ | | |

## 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** | | |
|---|---|---|
| ***Properties*** *(Inserted on form)* | ***New Tobacco Product*** *Name: Product A* | ***Predicate Tobacco Product*** *Name: Predicate A* |
| 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** | | | | |
|---|---|---|---|---|
| ***Properties*** *(Inserted on form)* | ***New Product 1*** *Name: Product A* *STN: N/A* | ***New Product 2*** *Name: Product B* *STN: N/A* | ***New Product 3*** *Name: Product C* *STN: N/A* | ***Predicate*** *Name: Predicate A* *STN: As Assigned by FDA* |
| Package Type | Box | Box | Box | Box |
| Package 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 | 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** | | |
| ***Co-Packaged Categories and Unique Identification Properties*** | ***New Tobacco Product(s)*** | |
| ***Category: Roll-Your-Own Subcategory: Roll-Your-Own Tobacco Filler*** | *Name: Component A* | *Name: Predicate A* |
| Package Type | Bag | Bag |
| Package Quantity | 100 g | 150 g |
| Characterizing Flavor | None | None |
| Additional Properties | Re-sealable Bag | Re-sealable Bag |
| ***Category: Roll-Your-Own Subcategory: Roll-Your-Own Rolling Paper*** | *Name: Component B* | *Name: Predicate B* |
| 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<br>(*except non-filtered*) |
| Characterizing Flavor | X |
| Additional Properties (if applicable) | X |

| Roll-Your-Own Tobacco Products | | | | | | | |
|---|---|---|---|---|---|---|---|
| ***Properties*** | ***Subcategories*** | | | | | | |
| | *Tobacco Filler* | *Rolling Paper* | *Filtered Cigarette Tube* | *Non-Filtered Cigarette Tube* | *Filter* | *Paper Tip* | *Other* |
| 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*** | | | | | |
| | *Component* | *Filtered Sheet-Wrapped* | *Unfiltered Sheet-Wrapped* | *Unfiltered Leaf-Wrapped* | *Tobacco Filler* | *Other* |
| 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*** | | | | | | | | |
| | *Loose Moist Snuff* | *Portioned Moist Snuff* | *Loose Snus* | *Portioned Snus* | *Loose Dry Snuff* | *Dissolvable* | *Loose Chewing* | *Portioned Chewing* | *Other* |
| 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*** | | | |
| | *Component* | *Pipe* | *Tobacco Filler* | *Other* |
| 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*** | | | | |
| | *Component* | *Waterpipe* | *Heat Source* | *Tobacco Filler* | *Other* |
| 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 |

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