

Product Name	Brand	Subbrand
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Enter Product Name, (or other commercial name(s) used in commercial distribution). The name listed here will be the name of the new products that will be listed in FDA correspondence.

Enter Brand Name - Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes. (this is from 1107.12 Definitions).

Enter Subbrand Name - Subbrand is a variety of tobacco product that is part of a larger, parent brand but has its own distinct identity, distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes. It may operate under the umbrella of the parent brand but may also have its own unique name, logo, and marketing strategy.

Limit to 500 characters including spaces.

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No special characters except percent sign (%), slash (/), period (.), ampersand (&), quotation marks (" "), apostrophe ('), colon (:), copyright symbol (©), parenthesis [()], Trademark (™), Registered Trademark (®).

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Manufacturer	TP Number	Package Type
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Enter Manufacturer Name - means any person, including any repacker or relabeler, who (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) Imports a finished tobacco product for sale or distribution in the United States. (this is from 1100.202 definitions).

This is the Tobacco Product Number issued from TRLM-NG when registration and listing is completed.

Select from drop-down list the packaging of the product (e.g., Soft Pack, Cartridge).

Limit to 500 characters including spaces.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If possible, avoid using "Other".

No special characters except percent sign (%), slash (/), period (.), ampersand (&), quotation marks (" "), apostrophe ('), colon (:), copyright symbol (©), parenthesis [()], Trademark (™), Registered Trademark (®).

Package Type, if Other	Product Quantity Numeric Value	Units (Product Quantity)
Only use if "Other" was selected for Package Type.	Provide the product quantity as a number, maximum of 7 digits.	Select product units from drop-down list for amount or number of products contained in the package (e.g., Bottles, Leaves).

Only use if "Other" was selected for Package Type.

Provide the product quantity as a number, maximum of 7 digits.

Select product units from drop-down list for amount or number of products contained in the package (e.g., Bottles, Leaves).

Enter a description of the package type for the product.

Provide a single value, cannot be a range. If possible, avoid using "Other".

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry cannot contain any letters. If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any special characters (refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Units, if Other (Product Quantity)	Product Quantity Mass Numeric Value	Units (Product Quantity Mass)
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Only use if "Other" was selected for Product Quantity Units.

Provide product quantity mass as a number, maximum of 7 digits.

Select product units from drop-down list for amount or number of products contained in the package (e.g., Milligrams, Grams).

Enter a description of the units for the product quantity. Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry should be concise and specific.

Entry cannot contain any letters.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Characterizing Flavor	Characterizing Flavor, If Flavored	Tobacco Cut Style
Select product flavor from the drop-down list (Menthol, Tobacco, Flavored, Unflavored).	Only use if "Flavored" was selected for Characterizing Flavor.	Select the tobacco cut style (e.g., Standard Cut, Pressed Cut) from drop-down list.

If "Flavored" selected, enter the concise flavor description in the next column.

Enter the Flavor that is identified on the package and labelling.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Limit to 500 characters including spaces.



No special characters except percent sign (%), slash (/), period (.), ampersand (&), quotation marks (" "), apostrophe ('), colon (:), copyright symbol (©), parenthesis [()], Trademark (™), Registered Trademark (®).

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Portion Count Numeric Value	Units (Portion Count)	Units, if Other (Portion Count)
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Provide portion count as a number, maximum of 7 digits.

Select from the drop-down list the unit of portions in the product (e.g., count, E-Cigarette, Tablet).

Only use if "Other" was selected for Portion Count Units.

Provide a single value, cannot be a range. If possible, avoid using "Other".

Enter description of the units for the Portion count.

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry cannot contain any letters.	If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.	If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.
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If you are populating the numeric value, you must provide the corresponding unit.

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Portion Mass Numeric Value	Units (Portion Mass)	Length Description
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Provide portion mass as a number, maximum of 7 digits.

Select product units from drop-down list for amount or number of products contained in the package (e.g., Milligrams, Grams).

Select from the drop-down list length description of the product (e.g., King, Long).

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

If possible, avoid using "Other".

Entry cannot contain any letters.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

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If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Length Description, if Other	Length Numeric Value	Units (Length)
Only use if "Other" was selected for Length Description.	Provide length of the product as a number, maximum of 7 digits.	Select unit of length from drop-down list of the product (e.g., Millimeters, Centimeters).

Only use if "Other" was selected for Length Description.

Provide length of the product as a number, maximum of 7 digits.

Select unit of length from drop-down list of the product (e.g., Millimeters, Centimeters).

Enter a description of the length of the product.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

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If you are populating the numeric value, you must provide the corresponding unit.



If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Width Numeric Value	Units (Width)	Diameter Description
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Provide width of the product as a number, maximum of 7 digits.

Select from the drop-down list unit of the width of the product (e.g., Millimeters, Centimeters).

Select from the drop-down list description of the diameter of the product (e.g. Regular, Wide).

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

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If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Diameter Format	Diameter Numeric Value	Units (Diameter)
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Select from the drop-down list format of the diameter (e.g., Circumference).

Provide diameter of the product as a number, maximum of 7 digits.

Select from the drop-down list unit of the diameter of the product (e.g., Millimeters, Centimeters).

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you are populating the Diameter Format column, you must provide the corresponding diameter numeric value and unit.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

For non-circular, rod-like, or rectangular products, diameter can be provided by calculating the maximum distance between two points of the product's borders; For rectangular products, Diameter=  $\sqrt{(\text{width})^2 + (\text{height})^2}$ .

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

For a rectangular product, a numerical value for diameter (e.g., 8mm) can be determined from the width and height of the product by reporting the measurement of the rectangle's diagonal where the reported diameter (i.e., the diagonal) equals the square root of the sum of the width squared and the height squared.

For a product that is neither rod-like nor rectangular, a numerical value for diameter (e.g., 8mm) can be provided as the maximum distance between two points of the product's borders.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Portion Thickness Numeric Value	Units (Portion Thickness)	Filter Ventilation
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Provide the portion thickness of the product as a number, maximum of 7 digits.

Select from the drop-down list unit of the portion thickness of the product (e.g., Millimeters, Centimeters).

Enter the filter ventilation (e.g., 0%, 25%).

Provide a single value, cannot be a range. If you are populating a column with units, you must provide the corresponding numeric value.

Only enter a number up to 100.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.



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Only enter positive numbers.

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Entry cannot contain any letters.

If you are populating the numeric value, you must provide the corresponding unit.

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If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

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E-liquid Volume	E-liquid Volume Units	Nicotine Concentration
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Enter the E-liquid volume as a number, maximum of 7 digits.

Select from the drop-down list e-liquid volume units (e.g., Milliliters, Fluid Ounces).

Provide the nicotine concentration of the product as a number, maximum of 7 digits.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

Provide a single value, cannot be a range.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

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If you are populating the numeric value, you must provide the corresponding unit.

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Nicotine Concentration Units	If mg/unit specify Unit (Nicotine Concentration)	Nicotine Source
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Select from the drop-down list nicotine concentration units (e.g., %W/W, mg/unit).

Only use if “mg/unit” was selected for Nicotine Concentration Units.

Select from the drop-down list nicotine source (e.g., Tobacco, Non-Tobacco, Both or None).

If you are populating a column with units, you must provide the corresponding numeric value.

Enter only unit for the nicotine concentration units.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

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If you are populating a column with units, you must provide the corresponding numeric value.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**PG Numeric Value**

**VG Numeric Value**

**Wattage Numeric Value**

Enter as a number the percentage of propylene glycol in the PG/VG ratio, maximum of 7 digits.

Enter as a number the percentage of vegetable glycerin in the PG/VG ratio, maximum of 7 digits.

Provide the wattage as a number, maximum of 7 digits.

Provide a single value, cannot be a range.

Provide a single value, cannot be a range.

Provide a single value, cannot be a range.

Only enter positive numbers.

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If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**Units (Wattage)**

**Battery Capacity Numeric Value**

**Units (Battery Capacity)**

Select from drop-down list units of wattage (e.g., Milliwatts, Volts).

Provide battery capacity as a number, maximum of 7 digits.

Select from drop-down list units of battery capacity (e.g., Watt, mAh).

If you are populating a column with units, you must provide the corresponding numeric value.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

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If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Tip Type	Tip Type, if Other	Wrapper Material
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Select from drop-down list tip type material (e.g., Wood, Paper).

Only use if "Other" was selected for Tip Type. Enter the tip material type.

Select from drop-down list Wrapper Material (e.g., Tobacco Leaf, Paper).

If possible, avoid using "Other".

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If possible, avoid using "other".

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**Wrapper Material, if Other**

**Number of Hoses**

**Source of Energy**

Only use if "other" was selected for Wrapper Material.

Provide the number of hoses as a number, maximum of 2 digits.

Select from the drop-down list the product source of energy (e.g., Charcoal, Battery).

Enter wrapper material type.

Provide a single value, cannot be a range. If possible, avoid using "Other".

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.



Source of Energy, if Other	Height Numeric Value	Units (Height)
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Only use if "Other" was selected for Source of Energy. Enter product source of energy.

Provide the height of the product as a number, maximum of 7 digits.

Select from the drop-down list units for the height of the product (e.g., Millimeters, Centimeters).

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Additional Properties (if Applicable)	Dates When Commercially Marketed in US Has this ever been marketed in the US?	Dates When Commercially Marketed in US 1st commercial market date (mm/dd/yyyy)
Enter any additional relevant product property information.	This question is asking if your new tobacco product has ever been marketed in the United States. Answer "yes" if this new tobacco product has been marketed in the United States in the past or today.	If your new tobacco product has been marketed in the United States, provide the date it was first commercially marketed in the US.

Maximum of 5,000.

Answer "yes" if this new tobacco product was previously marketed in the United States but is no longer marketed in the United States.

If your new tobacco product has never been marketed in the United States, leave this field blank.

Answer "yes" if this new tobacco product is currently being marketed in the United States.

Answer "yes" if this new tobacco product has been marketed in the United States in the past, removed from the market, and reintroduced.

Answer "no" if this new tobacco product has never been marketed in the United States.

<b>Dates When Commercially Marketed in US</b> <b>Is product currently marketed in the US?</b>	<b>Predicate</b>	<b>Original/Predicate STN PD Number</b>
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If your new tobacco product is currently marketed in the United States (i.e., as of the date you are submitting this form and application), answer "yes".

Enter Predicate, including brand and sub-brand (or other commercial name(s) used in commercial distribution).

If your new tobacco product was previously marketed in the United States but you stopped marketed (i.e., it is no longer marketed in the US), answer "no".

Limit to 500 characters including spaces.

If you have never marketed your new tobacco product in the United States, leave this field blank.

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Product Name	Brand	Subbrand
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Enter Product Name, (or other commercial name(s) used in commercial distribution). The name listed here will be the name of the new products that will be listed in FDA correspondence.

Enter Brand Name - Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes. (this is from 1107.12 Definitions).

Enter Subbrand Name - Subbrand is a variety of tobacco product that is part of a larger, parent brand but has its own distinct identity, distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes. It may operate under the umbrella of the parent brand but may also have its own unique name, logo, and marketing strategy.

For predicate products that are pre-existing tobacco product (PTP) determined or Claimed PTP provide the name as of February 15, 2007. For predicate products that are Previously Found SE provide the name as it appears in the marketing order.

Limit to 500 characters including spaces.

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Manufacturer	TP Number	Package Type
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Enter Manufacturer Name - means any person, including any repacker or relabeler, who (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) Imports a finished tobacco product for sale or distribution in the United States. (this is from 1100.202 definitions).

This is the Tobacco Product Number issued from TRLM-NG when registration and listing is completed.

Select from drop-down list the packaging of the product (e.g., Soft Pack, Cartridge).

Limit to 500 characters including spaces.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If possible, avoid using "Other".

No special characters except percent sign (%), slash (/), period (.), ampersand (&), quotation marks (" "), apostrophe ('), colon (:), copyright symbol (©), parenthesis [()], Trademark (™), Registered Trademark (®).

Package Type, if Other	Product Quantity Numeric Value	Units (Product Quantity)
Only use if "Other" was selected for Package Type.	Provide the product quantity as a number, maximum of 7 digits.	Select product units from drop-down list for amount or number of products contained in the package (e.g., Bottles, Leaves).

Only use if "Other" was selected for Package Type.

Provide the product quantity as a number, maximum of 7 digits.

Select product units from drop-down list for amount or number of products contained in the package (e.g., Bottles, Leaves).

Enter a description of the package type for the product.

Provide a single value, cannot be a range.

If possible, avoid using "Other".

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry cannot contain any letters.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any special characters (refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Units, if Other (Product Quantity)	Product Quantity Mass Numeric Value	Units (Product Quantity Mass)
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Only use if "Other" was selected for Product Quantity Units.

Provide product quantity mass as a number, maximum of 7 digits.

Select product units from drop-down list for amount or number of products contained in the package (e.g., Milligrams, Grams).

Enter a description of the units for the product quantity.

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry should be concise and specific. Entry cannot contain any letters.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry cannot contain any special characters (refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Characterizing Flavor	Characterizing Flavor, If Flavored	Tobacco Cut Style
Select product flavor from the drop-down list (Menthol, Tobacco, Flavored, Unflavored).	Only use if "Flavored" was selected for Characterizing Flavor.	Select the tobacco cut style (e.g., Standard Cut, Pressed Cut) from drop-down list.

If "Flavored" selected, enter the concise flavor description in the next column.

Enter the Flavor that is identified on the package and labelling.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory. Limit to 500 characters including spaces.

No special characters except percent sign (%), slash (/), period (.), ampersand (&), quotation marks (“”), apostrophe (’), colon (:), copyright symbol (©), parenthesis [()], Trademark (™), Registered Trademark (®).

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.



Portion Count Numeric Value	Units (Portion Count)	Units, if Other (Portion Count)
-----------------------------	-----------------------	---------------------------------

Provide portion count as a number, maximum of 7 digits.

Select from the drop-down list the unit of portions in the product (e.g., count, E-Cigarette, Tablet).

Only use if "Other" was selected for Portion Count Units.

Provide a single value, cannot be a range.

If possible, avoid using "Other".

Enter description of the units for the Portion count.

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

If you are populating a column with units, you must provide the corresponding numeric value.

Entry cannot contain any letters.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any special characters (refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Portion Mass Numeric Value	Units (Portion Mass)	Length Description
Provide portion mass as a number, maximum of 7 digits.	Select product units from drop-down list for amount or number of products contained in the package (e.g., Milligrams, Grams).	Select from the drop-down list length description of the product (e.g., King, Long).

Only enter positive numbers.

If you are populating a column with units, you must provide the corresponding numeric value.

If possible, avoid using "Other".

Entry cannot contain any letters.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Length Description, if Other	Length Numeric Value	Units (Length)
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Only use if "Other" was selected for Length Description.

Provide length of the product as a number, maximum of 7 digits.

Select unit of length from drop-down list of the product (e.g., Millimeters, Centimeters).

Enter a description of the length of the product.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.



Width Numeric Value	Units (Width)	Diameter Description
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Provide width of the product as a number, maximum of 7 digits.

Select from the drop-down list unit of the width of the product (e.g., Millimeters, Centimeters).

Select from the drop-down list description of the diameter of the product (e.g. Regular, Wide).

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Diameter Format	Diameter Numeric Value	Units (Diameter)
-----------------	------------------------	------------------

Select from the drop-down list format of the diameter (e.g., Circumference).

Provide diameter of the product as a number, maximum of 7 digits.

Select from the drop-down list unit of the diameter of the product (e.g., Millimeters, Centimeters).

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you are populating the Diameter Format column, you must provide the corresponding diameter numeric value and unit.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

For non-circular, rod-like, or rectangular products, diameter can be provided by calculating the maximum distance between two points of the product's borders; For rectangular products, Diameter= $\sqrt{(\text{width})^2 + (\text{height})^2}$ .

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

For a rectangular product, a numerical value for diameter (e.g., 8mm) can be determined from the width and height of the product by reporting the measurement of the rectangle's diagonal where the reported diameter (i.e., the diagonal) equals the square root of the sum of the width squared and the height squared.

For a product that is neither rod-like nor rectangular, a numerical value for diameter (e.g., 8mm) can be provided as the maximum distance between two points of the product's borders.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Portion Thickness Numeric Value	Units (Portion Thickness)	Filter Ventilation
---------------------------------	---------------------------	--------------------

Provide the portion thickness of the product as a number, maximum of 7 digits.

Select from the drop-down list unit of the portion thickness of the product (e.g., Millimeters, Centimeters).

Enter the filter ventilation (e.g., 0%, 25%).

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

Only enter a number up to 100.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

Entry cannot contain any letters.

Only enter positive numbers.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

Entry cannot contain any letters.

If you are populating the numeric value, you must provide the corresponding unit.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).



If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

<b>E-liquid Volume</b>	<b>E-liquid Volume Units</b>	<b>Nicotine Concentration</b>
------------------------	------------------------------	-------------------------------

Enter the E-liquid volume as a number, maximum of 7 digits.

Select from the drop-down list e-liquid volume units (e.g., Milliliters, Fluid Ounces).

Provide the nicotine concentration of the product as a number, maximum of 7 digits.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

Provide a single value, cannot be a range.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

Entry cannot contain any letters.

Entry cannot contain any letters.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Nicotine Concentration Units	If mg/unit specify Unit (Nicotine Concentration)	Nicotine Source
------------------------------	--	-----------------

Select from the drop-down list nicotine concentration units (e.g., %W/W, mg/unit).

Only use if "mg/unit" was selected for Nicotine Concentration Units.

Select from the drop-down list nicotine source (e.g., Tobacco, Non-Tobacco, Both or None).

If you are populating a column with units, you must provide the corresponding numeric value.

Enter only unit for the nicotine concentration units.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you are populating a column with units, you must provide the corresponding numeric value.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**PG Numeric Value**

**VG Numeric Value**

**Wattage Numeric Value**

Enter as a number the percentage of propylene glycol in the PG/VG ratio, maximum of 7 digits.

Enter as a number the percentage of vegetable glycerin in the PG/VG ratio, maximum of 7 digits.

Provide the wattage as a number, maximum of 7 digits.

Provide a single value, cannot be a range.

Provide a single value, cannot be a range.

Provide a single value, cannot be a range.

Only enter positive numbers.

Only enter positive numbers.

Only enter positive numbers.

Entry cannot contain any letters.

Entry cannot contain any letters.

Entry cannot contain any letters.

Entry cannot contain any special characters (refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

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If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you are populating the numeric value, you must provide the corresponding unit.



If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**Units (Wattage)**

**Battery Capacity Numeric Value**

**Units (Battery Capacity)**

Select from drop-down list units of wattage (e.g., Milliwatts, Volts).

Provide battery capacity as a number, maximum of 7 digits.

Select from drop-down list units of battery capacity (e.g., Watt, mAh).

If you are populating a column with units, you must provide the corresponding numeric value.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Tip Type	Tip Type, if Other	Wrapper Material
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Select from drop-down list tip type material (e.g., Wood, Paper).

Only use if "Other" was selected for Tip Type. Enter the tip material type.

Select from drop-down list Wrapper Material (e.g., Tobacco Leaf, Paper).

If possible, avoid using "Other".

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If possible, avoid using "other".

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**Wrapper Material, if Other**

**Number of Hoses**

**Source of Energy**

Only use if "other" was selected for Wrapper Material.

Provide the number of hoses as a number, maximum of 2 digits.

Select from the drop-down list the product source of energy (e.g., Charcoal, Battery).

Enter wrapper material type.

Provide a single value, cannot be a range.

If possible, avoid using "Other".

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Entry cannot contain any letters.

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Source of Energy, if Other	Height Numeric Value	Units (Height)
Only use if "Other" was selected for Source of Energy. Enter product source of energy.	Provide the height of the product as a number, maximum of 7 digits.	Select from the drop-down list units for the height of the product (e.g., Millimeters, Centimeters).

Only use if "Other" was selected for Source of Energy. Enter product source of energy.

Provide the height of the product as a number, maximum of 7 digits.

Select from the drop-down list units for the height of the product (e.g., Millimeters, Centimeters).

If you did not select "other" then you must leave this cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

If you are populating a column with units, you must provide the corresponding numeric value.

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.



Entry cannot contain any letters

Entry cannot contain any special characters  
(refer to the Electronic Submission File Formats and Specifications which can be found on the FDA website).

If you are populating the numeric value, you must provide the corresponding unit.

If you do not have values for a field, you must leave the cell blank. Please refer to 21 CFR 1107.8 for the required properties based on product category and subcategory.

**Additional Properties (if Applicable)**

<b>Dates When Commercially Marketed in US</b> <b>Has this ever been marketed in the US?</b>	<b>Dates When Commercially Marketed in US</b> <b>1st commercial market date (mm/dd/yyyy)</b>
--	---

Enter any additional relevant product property information.

This question is asking if your predicate tobacco product has ever been marketed in the United States. Answer "yes" if this predicate tobacco product has been marketed in the United States in the past or today.

If your predicate tobacco product has been marketed in the United States, provide the date it was first commercially marketed in the US.

Maximum of 5,000.

Answer "yes" if this predicate tobacco product was previously marketed in the United States but is no longer marketed in the United States.

If your predicate tobacco product has never been marketed in the United States, leave this field blank.

Answer "yes" if this predicate tobacco product is currently being marketed in the United States.

Answer "yes" if this predicate tobacco product has been marketed in the United States in the past, removed from the market, and reintroduced.

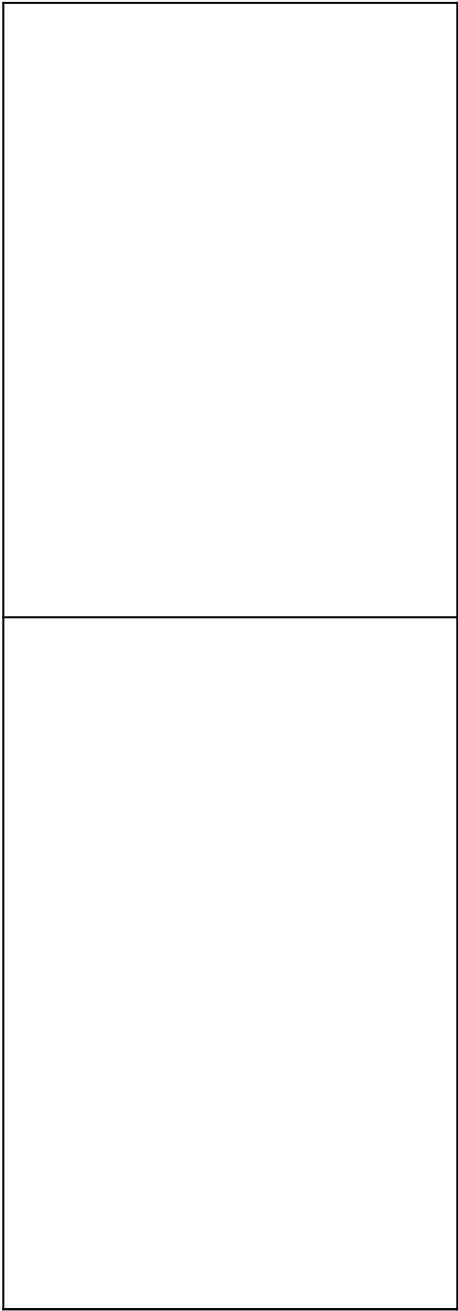
Answer "no" if this predicate tobacco product has never been marketed in the United States.


**Dates When Commercially Marketed  
in US**  
**Is product currently marketed in the  
US?**

If your predicate tobacco product is currently marketed in the United States (i.e., as of the date you are submitting this form and application), answer "yes".

If your predicate tobacco product was previously marketed in the United States but you stopped marketed (i.e., it is no longer marketed in the US), answer "no".

If you have never marketed your predicate tobacco product in the United States, leave this field blank.



# Unique

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## **Instructions:**

1. Applicant name must be entered c
2. Product Category must be entered c
3. Product Subcategory must be ente
4. To populate your unique identifica subcategory, and application type, cl a new tab called "Product" to genera
5. Complete product tab for all tobac each product property for ingestion. Product Tab.
6. If you click on the "reset" button y
7. Once you have completed data eni file naming convention, reference the
8. Your spreadsheet must be XLS or X
9. Create a separate spreadsheet for validate. If total number of products additional products.
10. Only use this spreadsheet for PM

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## **Product Information**

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**Applicant Name**

**Product Category**

**Product Subcategory**

**Application Type**

---

Version: 1.0

Release Date: TBD



## Identifying Information for New Tobacco Products

as required by 21 CFR § 1114.7(c)(3).

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ered as required by 21 CFR § 1114.7(c)(3). To ensure ingestion use the drop-down menu.

tion of your products, once you have completed entry of applicant name, product category, product  
ick on the "Enter Unique Product Properties" button to enter each tobacco product. This will allow for  
ite.

co products you are submitting. Refer to the "Instructions Tab" for information to correctly populate  
Enter applicable product information as specified in Table 1 to 21 CFR § 1114.7(c)(3)(iii) under the

ou will lose your product tab and all product data entered.

try for both your introduction and product tabs, SAVE AS .XLS or .XLSX and name appropriately. For

Electronic Submission File Formats and Specifications which can be found on the FDA website.

.XLSX to attach to eSubmitter file for submission, otherwise it will not be processed.

each product Category/Subcategory. Do not exceed 5000 rows of products as the spreadsheet will not  
for each product Category/Subcategory exceeds 5000 products, then create a new spreadsheet for the

TA submissions.

**Please not**

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SE

# FDA Form 3965b

OMB Control No. 0910-0673  
Expiration Date: XX/XX/20XX  
See PRA Statement on  
bottom of page

**e:**

g as an .xls or .xlsx will cause all drop down menus to  
, so be certain you are completely finished. Your data will  
but you will not have drop down functions if you must re-  
open.

ming convention, reference the Electronic Submission File  
nd Specifications which can be found on the FDA website.