

Product Name	TP Number
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Enter Product Name, including brand and sub-brand (or other commercial name(s) used in commercial distribution).

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

Limit to 500 characters including spaces.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

No special characters except percent sign (%), slash (/), period (.), ampersand (&), quotation marks (" "), apostrophe ('), colon (:), copyright symbol (©).

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

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

If possible, avoid using "Other".

Enter a description of the package type for the product.

If you did not select "other" then you must leave this cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Product Quantity Numeric Value	Units (Product Quantity)
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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).

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

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Units, if Other (Product Quantity)	Product Quantity Mass Numeric Value
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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.

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

Entry should be concise and specific.

Entry cannot contain any letters.

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

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

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

Select product flavor from the drop-down list (Menthol, Tobacco, Flavored, Unflavored).

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

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

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

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Characterizing Flavor, If Flavored	Tobacco Cut Style
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Only use if "Flavored" was selected for Characterizing Flavor.

Select the tobacco cut style (e.g., Standard Cut, Pressed Cut) from drop-down list.

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 (©).

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Portion Count Numeric Value	Units (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).

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

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Units, if Other (Portion Count)	Length Description
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Only use if "Other" was selected for Portion Count Units.

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

Enter description of the units for the Portion count.

If possible, avoid using "Other".

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Length Description, if Other	Length Numeric Value
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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.

Enter a description of the length of the product.

Provide a single value, cannot be a range.

If you did not select "other" then you must leave this cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Only enter positive numbers.

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Units (Length)	Width Numeric Value
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Select unit of length from drop-down list of the product (e.g., Millimeters, Centimeters).

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

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 do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Only enter positive numbers.

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.

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Units (Width)	Diameter Description
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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).

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

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Diameter Format	Diameter Numeric Value
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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.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

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

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.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Units (Diameter)	Portion Thickness Numeric Value
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Select from the drop-down list unit of the diameter of the product (e.g., Millimeters, Centimeters).

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

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 do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Only enter positive numbers.

Entry cannot contain any letters.

Entry cannot contain any special characters
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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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Units (Portion Thickness)	Filter Ventilation
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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%).

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

Only enter a number up to 100.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

Only enter positive numbers.

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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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

E-liquid Volume	E-liquid Volume Units
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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 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

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

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

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

If mg/unit specify Unit (Nicotine Concentration)	Nicotine Source
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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).

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

PG Numeric Value

VG 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 a single value, cannot be a range.

Provide a single value, cannot be a range.

Only enter positive numbers.

Only enter positive numbers.

Entry cannot contain any letters.

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Wattage Numeric Value**Units (Wattage)**

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

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

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Battery Capacity Numeric Value Units (Battery Capacity)

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

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

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Tip Type	Tip Type, if Other
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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.

If possible, avoid using "Other". If you did not select "other" then you must leave this cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Wrapper Material	Wrapper Material, if Other
Select from drop-down list Wrapper Material (e.g., Tobacco Leaf, Paper).	Only use if "other" was selected for Wrapper Material.

If possible, avoid using "other". Enter wrapper material type.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Number of Hoses

Source of Energy

Provide the product quantity as a number, maximum of 2 digits.

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

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

Only enter positive numbers.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Recordkeeping Requirements rule for the required properties based on product category and subcategory.

Source of Energy, if Other

Height Numeric Value

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.

If you did not select "other" then you must leave this cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Provide a single value, cannot be a range.

Only enter positive numbers.

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Units (Height)	Additional Properties (if Applicable)
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Select from the drop-down list units for the height of the product (e.g., Millimeters, Centimeters). Enter any additional relevant product property information.

If you are populating a column with units, you must provide the corresponding numeric value. Maximum of 5,000.

If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record keeping Requirements rule for the required properties based on product category and subcategory.

Unique

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. i Product Tab.
6. If you click on the "reset" button yc
7. Once you have completed data ent naming convention, reference the Ele
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'

Product Information

Applicant Name

Product Category

Product Subcategory

Application Type

Version: 3.0

Release Date: September 2023

This section applies only to requirem
*DO NOT SEND YOUR COMPLETED F
The burden time for this collection of
and complete and review the collecti
following email address:
For PRA questions:
PRAS^taff@fda.hhs.gov
OMB Statement: "An agency may no

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 file
ctronic 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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PMTA

ents of the Paperwork Reduction Act of 1995.

ORM TO THE PRA STAFF ADDRESS BELOW.*

f information is estimated to average 35 minutes per response, including the time to review instructions, search ex
ion of information. Send comments regarding this burden estimate or any other aspect of this information collecti

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Expiration Date: 12/31/2025
See PRA Statement on
bottom of page

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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.

existing data sources, gather and maintain the data needed on, including suggestions for reducing this burden, to the

currently valid OMB number.”