

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 1114.3 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 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.

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 (Product Quantity Mass)	Characterizing Flavor	Characterizing Flavor, If Flavored
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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).

Only use if "Flavored" was selected for Characterizing Flavor.

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.

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.

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Limit to 500 characters including spaces.

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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.

Tobacco Cut Style	Portion Count Numeric Value	Units (Portion Count)
Select the tobacco cut style (e.g., Standard Cut, Pressed Cut) from drop-down list.	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).

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 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)	Portion Mass Numeric Value	Units (Portion Mass)
Only use if "Other" was selected for Portion Count Units.	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).

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

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).

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.

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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.

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.

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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Length Description	Length Description, if Other	Length Numeric Value
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Select from the drop-down list length description of the product (e.g., King, Long).

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

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

If possible, avoid using "Other".

Enter a description of the length of the product.

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.

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.

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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 (Length)	Width Numeric Value	Units (Width)
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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.

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

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

Diameter Description	Diameter Format	Diameter Numeric Value
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Select from the drop-down list description of the diameter of the product (e.g. Regular, Wide).

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.

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 Format column, you must provide the corresponding diameter numeric value and unit.

Only enter positive numbers.

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 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	Units (Portion Thickness)
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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.

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

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 the Premarket Tobacco Product Applications and Record keeping Requirements rule 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 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.

Filter Ventilation	E-liquid Volume	E-liquid Volume Units
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Enter the filter ventilation (e.g., 0%, 25%).

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).

Only enter a number up to 100.

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 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.

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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.

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

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

Provide a single value, cannot be a range.

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

Enter only unit for the nicotine concentration units.

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.

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.

Nicotine Source	PG Numeric Value	VG Numeric Value
Select from the drop-down list nicotine source (e.g., Tobacco, Non-Tobacco, Both or None).	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.

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.

Provide a single value, cannot be a range.

Only enter positive numbers.

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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 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 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.

Wattage Numeric Value

Units (Wattage)

Battery Capacity Numeric Value

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

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

Provide battery capacity 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 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.

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

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Units (Battery Capacity)

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

Tip Type

Select from drop-down list tip type material (e.g., Wood, Paper).

Tip Type, if Other

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

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

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.

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Wrapper Material	Wrapper Material, if Other	Number of Hoses
Select from drop-down list Wrapper Material (e.g., Tobacco Leaf, Paper).	Only use if "other" was selected for Wrapper Material.	Provide the number of hoses as a number, maximum of 2 digits.

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

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 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

Source of Energy, if Other

Height Numeric Value

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

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 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.

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.

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)	Dates When Commercially Marketed in US Has this ever been marketed in the US?
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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.

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

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 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.

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 product has never been marketed in the United States.

Dates When Commercially Marketed in US 1st commercial market date (mm/dd/yyyy)	Dates When Commercially Marketed in US Is product currently marketed in the US?
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If your new tobacco product has been marketed in the United States, provide the date it was first commercially marketed in the US.

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".

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

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

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

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. 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

Product Information

Applicant Name

Product Category

Product Subcategory

Application Type

Version: 3.1

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.

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Formats a

PMTA

FDA Form 4057b

OMB Control No. 0910-0879
Expiration Date: XX/XX/20XX
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.