

FDA Center for Tobacco Products (CTP)

## Instructions for Listing of Ingredients in Tobacco Products

March 5, 2018

**Please read through all the steps listed below before you begin.**

These instructions were developed to help tobacco product manufacturers prepare product and ingredient listings to submit to FDA via eSubmitter. There are several steps to the process, but if you follow these instructions and FDA recommendations, the result will be product and ingredient spreadsheets that meet FDA requirements (under Sections 904(a)(1), 904(c)(1), 904(c)(2), or 904(c)(3)), and give you useful information as well.

We recommend that you use both FDA's eSubmitter software and the CTP Portal:

- If you don't have a CTP Portal account, please request one [here](#).
- Download and install [eSubmitter](#), if you have not already done so.

### OVERVIEW

Here is an overview of the steps you will need to take:

**Step 1.** Create a new submission in eSubmitter using the CTP: Tobacco Product Ingredient Listing submission type.

**Step 2.** Enter product and ingredient information using one of four options:

- a. Enter product, component, and ingredient information manually into eSubmitter.
- b. Enter product and ingredient information using two CTP-provided spreadsheets, and enter component information manually.
- c. Attach product, component, and ingredient information using a single CTP-provided spreadsheet.
- d. Attach your own spreadsheet.

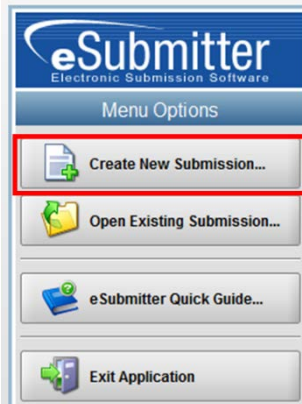
**Step 3.** Package your submission files.

**Step 4.** Transmit your packaged submission to FDA using CTP Portal (preferred).

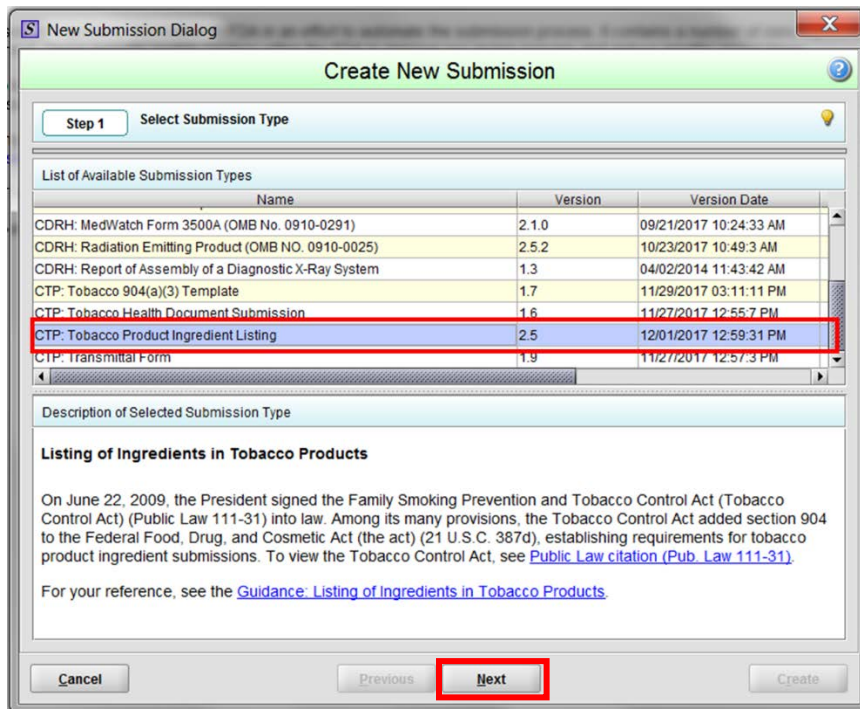
**DETAILED INSTRUCTIONS**

**Step 1 – Create a new submission in eSubmitter using the CTP: Tobacco Product Ingredient Listing submission type.**

- a. Open the eSubmitter application on your computer.
- b. Click on the Create New Submission button in the Menu Options on the left side of the screen.



- c. Scroll down the list of submission options until you find CTP: Tobacco Product Ingredient Listing. Click on it once to highlight it and then click Next.





- d. Describe and name the file. Use of special characters or non-English characters that are not recognized by CTP's Windows operating system cause processing to fail (@, #, \$, %, ^, &, \*, (, ), ~, +). CTP recommends a file name length of 50 characters or less. Click the Create button in the bottom right part of the screen.
- e. Read the on-screen instructions and choose your Submission Type, then click the right arrow at the bottom of the screen.

Submission Type (Please ensure that all products under this submission meet the definition of the checked submission type. Click lightbulb for definitions)

- Type a: Initial submission per 904(a)(1) for product(s) on the market as of June 22, 2009 (for cigarettes, cigarette tobacco, RYO, and smokeless tobacco) or August 8, 2016 (for other tobacco products)
- Type b: Initial submission per 904(c)(1) for new product(s)
- Type c: Initial submission per 904(c)(1) for modification to existing product(s)
- Type d: Initial submission per 904(c)(2) for modification to existing product(s)\*
- Type e: Initial submission per 904(c)(3) for modification to existing product(s)\*
- Type f: Amendment to correct previous product ingredient submission(s)\*\*



- f. Indicate whether you are a Manufacturer or an Importer, then click the right arrow.
- g. Enter information about your company. Remember that a blue dot next to a field means it is required information. Click the right arrow.

Next you will complete your Tobacco Product Ingredient Listings using one of four options listed in the overview on Page 1.

Click on the links below to go to detailed instructions for the option you would like to use:

- [Step 2 – Option a. Enter product, component, and ingredient information manually.](#)
- [Step 2 – Option b. Enter product and ingredient information using two CTP-provided spreadsheets.](#)
- [Step 2 – Option c. Attach product, component, and ingredient information on a single spreadsheet.](#)
- [Step 2 – Option d. Attach your own spreadsheet.](#)

**Step 2 – Option a. Enter product, component, and ingredient information manually.**

- 1) On the next screen click the top radio button, read the on-screen instructions, and then click the right arrow.

How will you provide Product, Component, Ingredient, and Identical Product Information?

- a) Enter product, component, and ingredient information manually on the following screens
- b) Enter product and ingredient information using separate CTP-provided spreadsheets, and enter component information manually
- c) Attach product, component, and ingredient information using a single CTP-provided spreadsheet
- d) Attach your own spreadsheet

For option A:

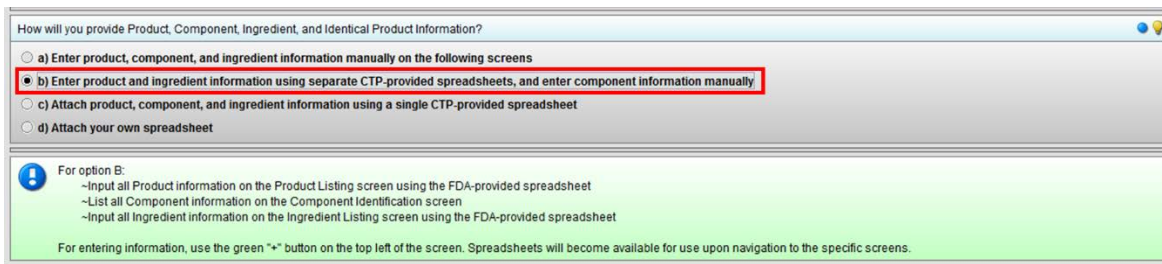
- List all Product information on the Product Listing screen
- List all Component information on the Component Identification screen
- List all Ingredient information on the Ingredient Listing screen

To accomplish this, use the green '+' button on the top left of the above 3 screens.

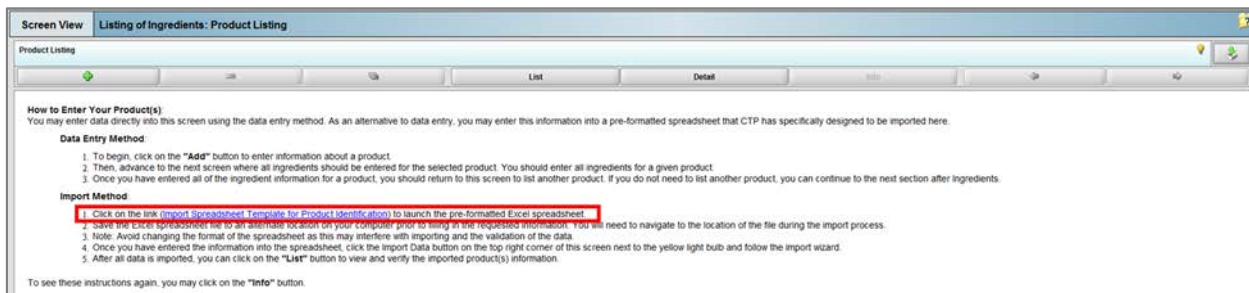
- 2) Follow the on-screen instructions to manually enter your product and ingredient information.

**Step 2 – Option b. Enter product and ingredient information using two CTP-provided spreadsheets.**

- 1) On the next screen click the second radio button (b) to list products on one spreadsheet and ingredients on a second spreadsheet. Note: if you select this option you will need to enter component and identical product information manually. Click the right arrow.



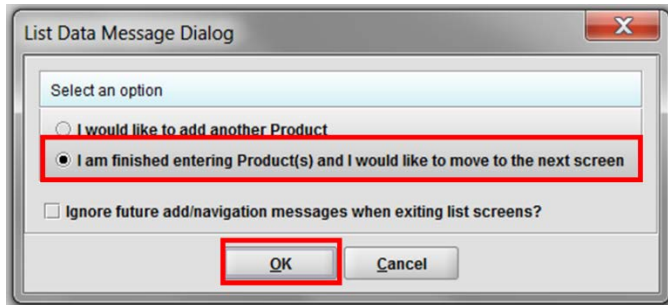
- 2) Click on the link for the products spreadsheet and save it to your computer. Enter your product information into the spreadsheet. Save the spreadsheet every few minutes to avoid data loss.



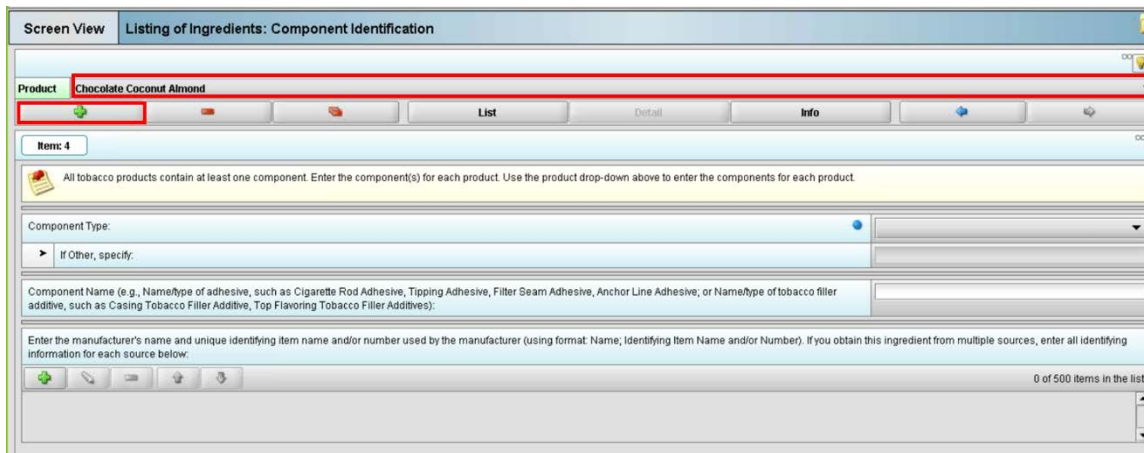
- 3) Once you have entered all your products into your spreadsheet, upload the spreadsheet to eSubmitter by clicking on the Upload Data icon in the upper right part of the screen next to the Help lightbulb.



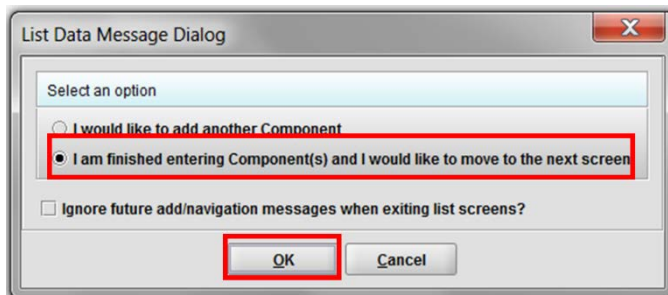
- 4) Click the right arrow. When you get the pop-up box select the second radio button and click OK.



- 5) On the next screen enter component information for each product. If you don't enter component information, you will not be able to upload an ingredient spreadsheet.
- 6) Click on the Product Name and choose the product from the drop-down list. Then click the green plus sign to enter components associated with that product. Repeat this process for all products.



- 7) Once you are done entering components, click the right arrow, and when you get the pop-up box select the second radio button and click OK.



- Click on the link for the ingredients spreadsheet and save it to your computer. Enter your ingredient information into the spreadsheet. Save the spreadsheet every few minutes to avoid data loss.

**How to Enter the Ingredient Information for each Product**  
 List all ingredients for the product that was entered and selected in the previous screen (displayed in the "Product" header above). To facilitate data entry, please enter reaction products after entering all other ingredients.  
 You may enter data directly into this screen using the data entry method. As an alternative to data entry, you may enter this information into a pre-formatted spreadsheet that CTP has specifically designed to be imported here.

**Data Entry Method:**

- To begin, click on the "Add" button to enter information on a particular ingredient.
- Once you have entered the information about a particular ingredient, click on the "Add" button to enter information about another ingredient.
- Repeat steps 1 and 2 until all ingredients have been entered for the product identified above.
- After you have entered all ingredients for the selected product, return to the Product Identification screen to enter another product. Select the next product in the List and advance to this screen to add the ingredient information.

**Import Method:**

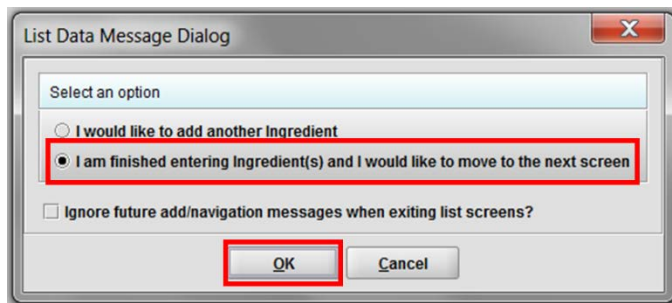
- You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link [\(Import Spreadsheet Template for Ingredient Identification\)](#) to launch the pre-formatted Excel spreadsheet.
- Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information. You will need to navigate to the location of the file during the import process.
- Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
- Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner of this screen next to the yellow light bulb and follow the import wizard.
- After all data is imported, you can click "List" to view and verify the imported product(s) information.

To see these instructions again, you may click on the "Info" button above.

- Once you have entered all your ingredient information into the spreadsheet, upload the spreadsheet to eSubmitter by clicking on the Upload Data icon in the upper right part of the screen next to the Help lightbulb.

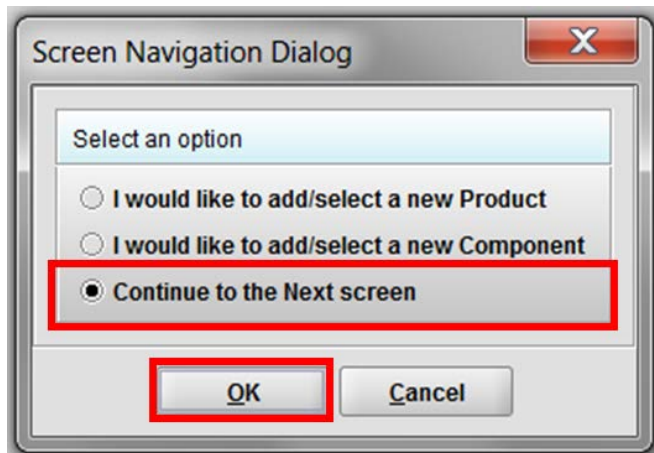


- Click the right arrow. When you get the pop-up box select the second radio button and click OK.

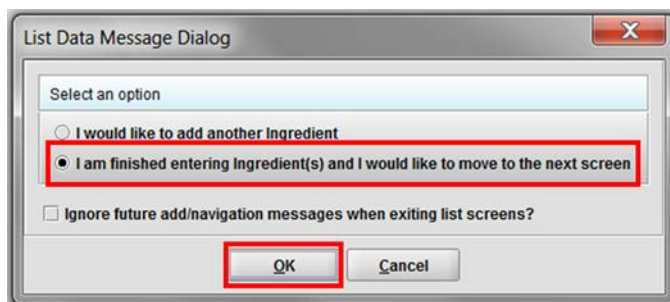


- At the next pop-up select the last radio button and click OK.

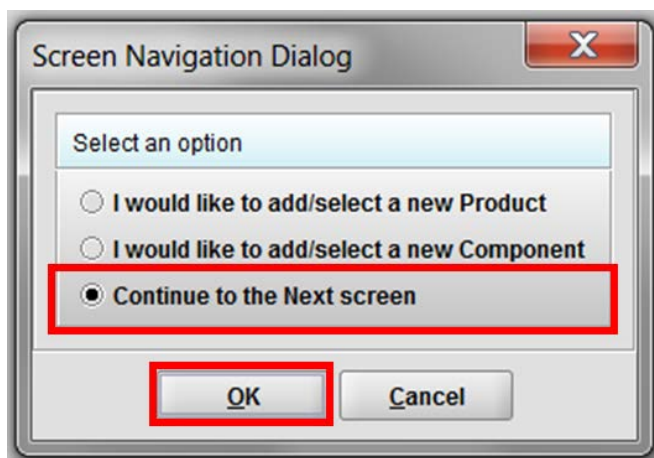




- 12) Enter Identical Product information, as applicable. When you are done, click the right arrow.
- 13) When you get the pop-up box select the second radio button and click OK.

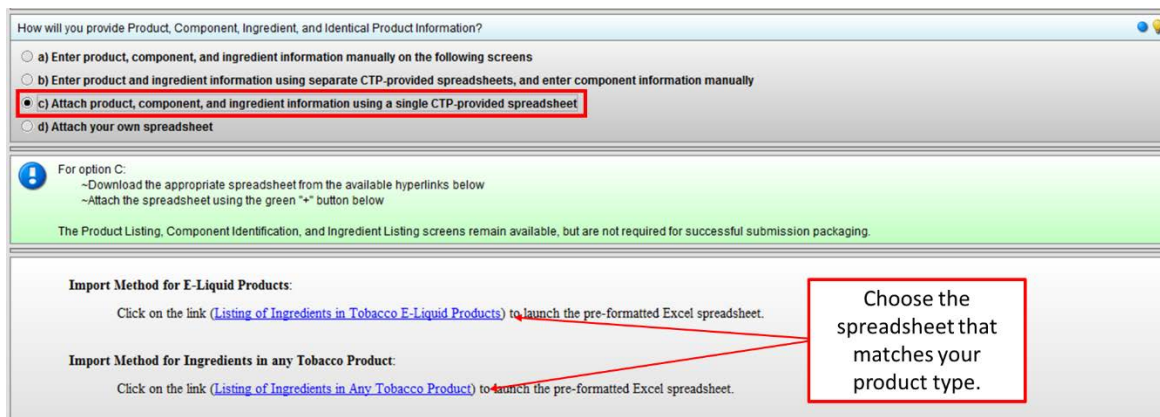


- 14) At the next pop-up select the last radio button and click OK.

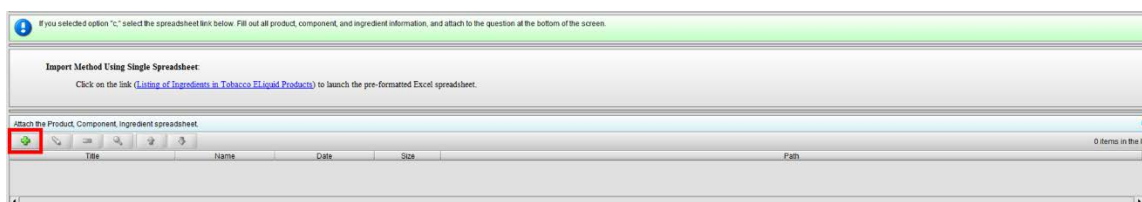


**Step 2 – Option c. Attach product, component, and ingredient information on a single spreadsheet.**

- 1) Select the third radio button and then click on the link to open the combined product, component, and ingredient spreadsheet that matches the product type for your submission.



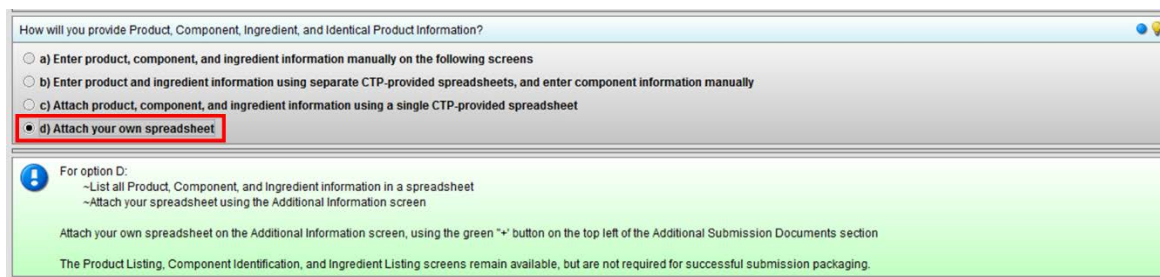
- 2) Save the spreadsheet to your computer and give it a meaningful name. Enter your ingredient information into the spreadsheet. Save the spreadsheet every few minutes to avoid data loss.
- 3) When you are done entering all your product, component, and ingredient information into the spreadsheet, click on the green arrow under the spreadsheet links in eSubmitter to attach the spreadsheet to your submission package.



- 4) Click the right arrow.

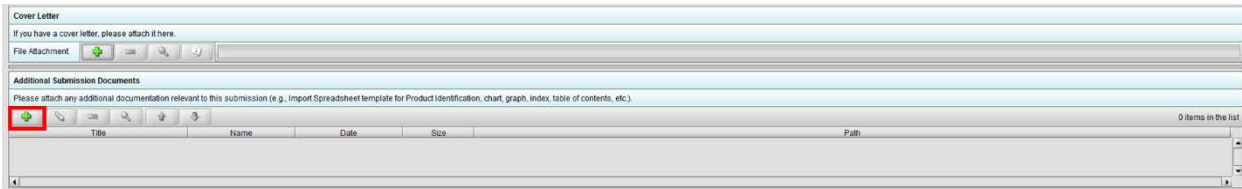
**Step 2 – Option d. Attach your own spreadsheet.**

- 1) Click the fourth radio button.



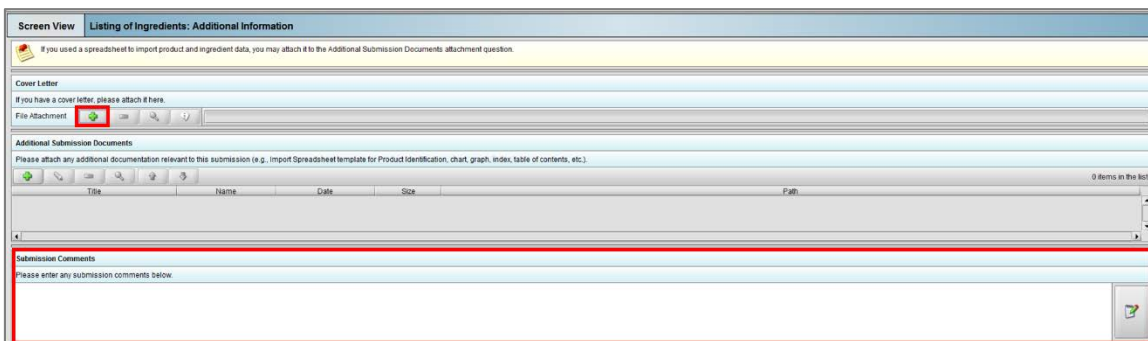


- 2) Click the right arrow until you come to the screen called Listing of Ingredients: Additional Information. When pop-up boxes appear, just click OK.
- 3) On the Additional Information screen, click the green plus sign under Additional Submission Documents and follow the on-screen instructions to attach your spreadsheet.



**Step 3 – Package your Submission Files.**

- a. The Listing of Ingredients: Additional Information screen is where you can attach a cover letter or enter comments related to your submission. These are optional, but give you ways to communicate additional information about your submission to FDA. For example, if a Tobacco Product Master File (TPMF) will be used as part of your 904(a)1 submission, consider referring to the [TPMF Guidance](#) for items you could include in your submission (e.g., written authorization for right of reference, TPMF number, and a brief description of the content of the TPMF).
- b. To attach a cover letter, click the green plus sign and follow the on-screen instructions.
- c. To enter comments, click in the comments box and type.



- d. Click the right arrow, proceed to the Confirmation Statement screen, and enter the requested information. When you are done, click the right arrow.
- e. On the Package Files for Submission screen, click on the Output pull-down menu from the top tool bar and select Package Submission Files.



- f. Follow the on-screen instructions to finish packaging your submission. For more details please consult the detailed [eSubmitter instructions](#) document.

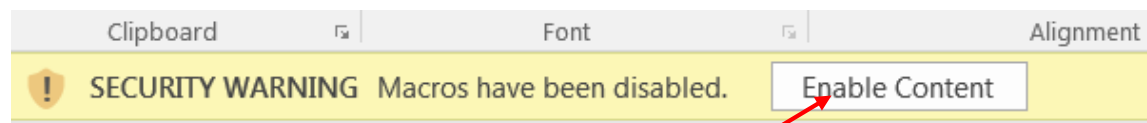
**Step 4 – Transmit your Packaged Submission to FDA using CTP Portal (preferred).**

### How to Enable Macros in an Excel Spreadsheet

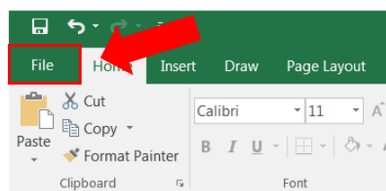
Some CTP-provided spreadsheets include macros that perform mathematical calculations, auto populate drop-down lists, and create or delete workbook tabs, but for these to work, you must enable macros.

We used macros to make entering information as easy as possible. Follow these steps to enable macros:

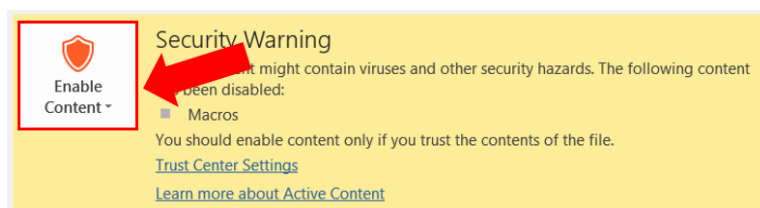
1. When you open the spreadsheet, you will see a yellow banner across the top.



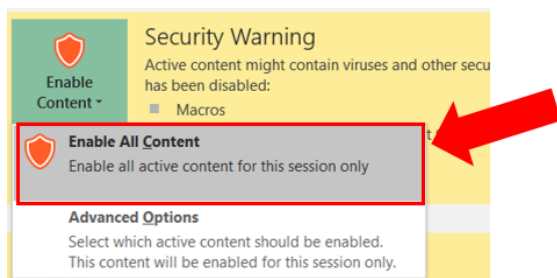
2. Click on the Enable Content button to enable macros.
3. If you closed the warning without enabling the macros, you will get an error message when you click on the Create Individual Ingredient Submission Sheets button.
4. Do the following to enable macros:
  - a. Click on File at the top left corner of the spreadsheet.



- b. At the top of the Info page, click on Enable Content.



- c. Select Enable All Content.



- d. Macros are now enabled.



## List of URLs Referenced in these Instructions:

Request an Industry Account Manager (IAM) for CTP Portal

<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515185.htm>

CTP – Prepare regulatory documents to submit online

<https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm189469.htm>

eSubmitter Tutorials

<https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm193862.htm>

FDA Guidance for Tobacco Products

<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm>

Listing of Ingredients in Tobacco Products Guidance for Industry

<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM527044.pdf>

FDA eSubmitter Quick Guide

<https://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM449759.pdf>

FDA eSubmitter User Manual

<https://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM449686.pdf>

Tobacco Product Master Files Guidance for Industry

<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499350.pdf>