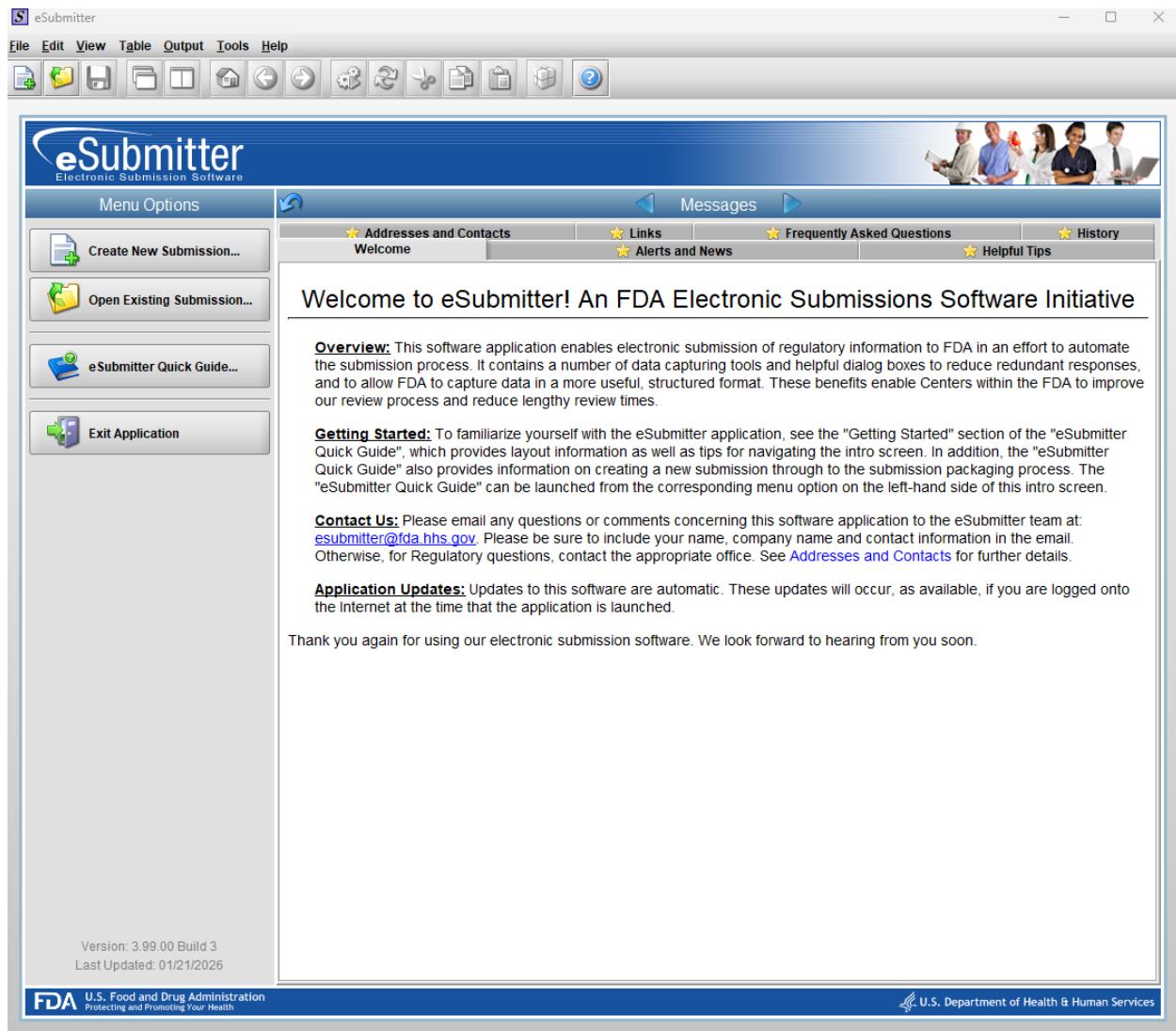
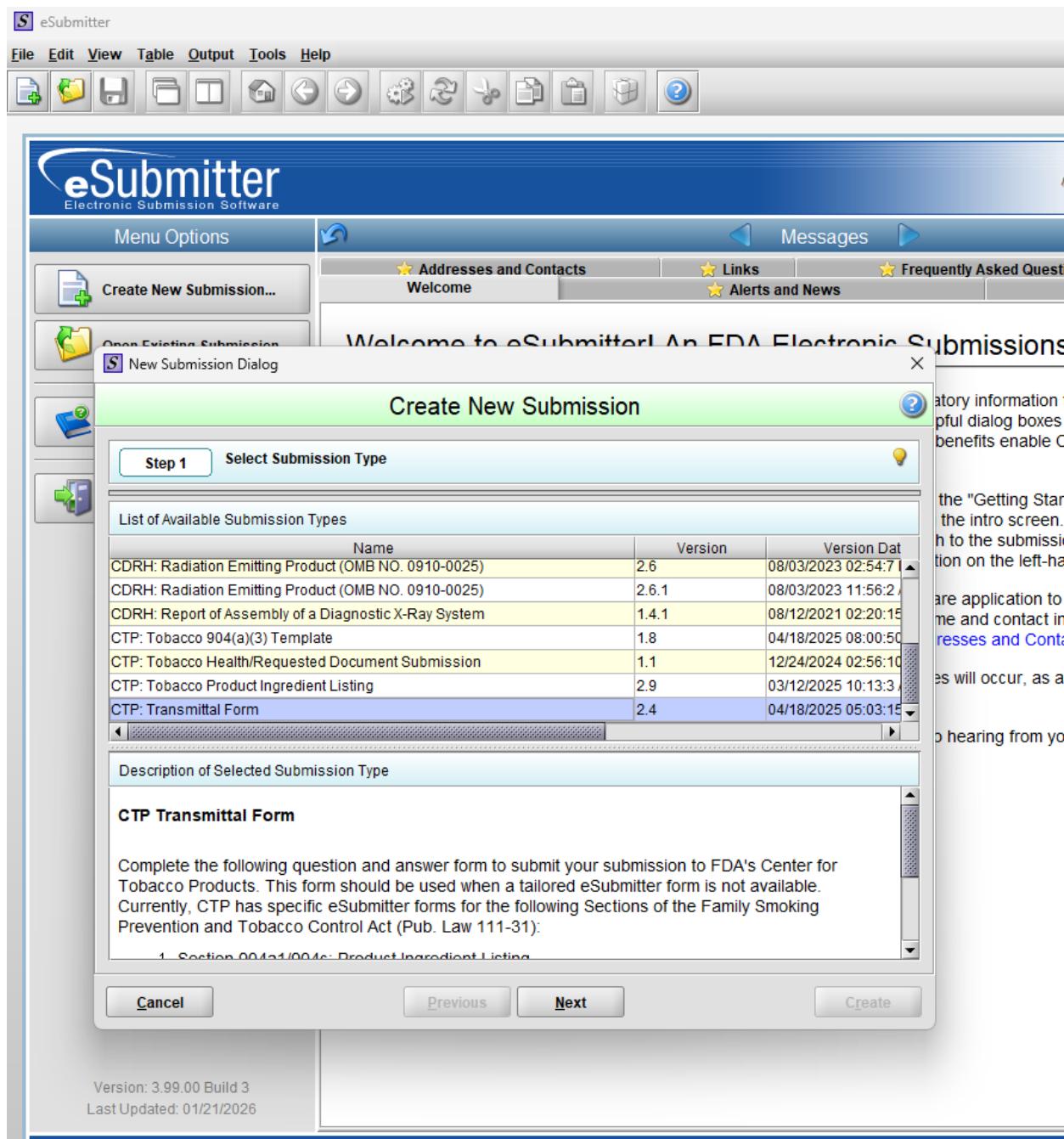


## Steps to submit a new Warning Plan:

### 1. Launch eSubmitter



If a user is creating a new submission, they can click the create new submission button. They would select the “CTP: Transmittal Form” option.



Once they select CTP: Transmittal Form, the following Create New Submission dialog will appear. Note that anything with a blue button beside the field is mandatory. In this case, file name and descriptive name are mandatory.

**S** New Submission Dialog X

### Create New Submission

Step 2 Provide Submission Details ?

**Specify the Submission Descriptive and File Names** ?

|   |                  |   |  |
|---|------------------|---|--|
| • | Descriptive Name | ● | <input type="text" value="Sample_WP"/> |
| • | File Name (.xml) | ● | <input type="text" value="Sample_WP"/> |

**Additional Comments about this Submission** ?

This field is optional.

This is a sample submission regarding warning plans for OCE.

Cancel Previous Next Create

If a user wishes to continue work on an existing submission, choose the existing submission option to see a list of draft esubmitter files.

**S** Open Submission Dialog X

### Open Existing Submission

?

| Select Submission to Open | [Note: double-click column header to change sort, (a)scending, (d)escending ] |
|---------------------------|---|
| Submission Name (a)       |   |
| Sample_WP                 | [Select]  |
| ◀ ▶                       |   |

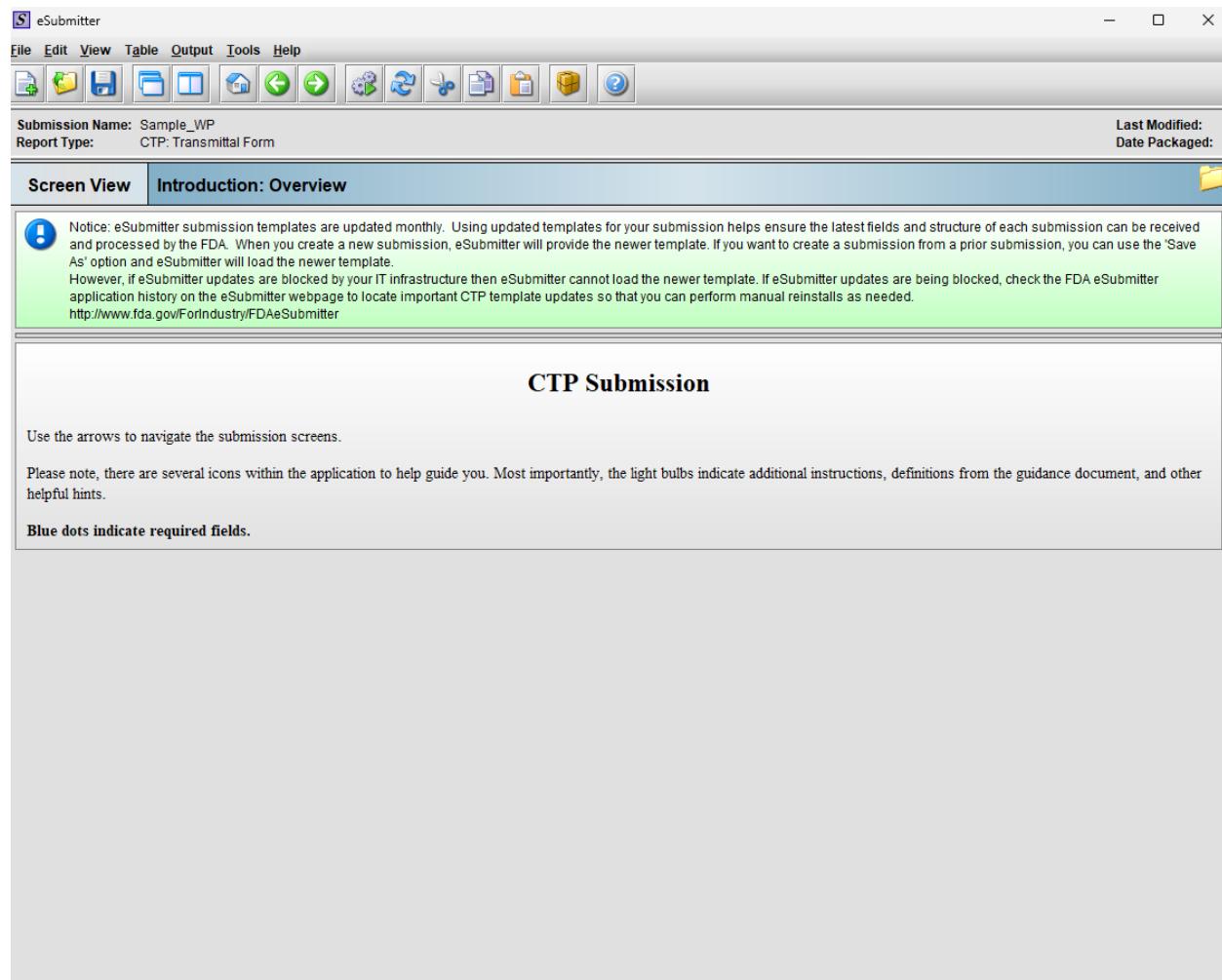
**View the Description of the Selected Submission**

This field is optional.

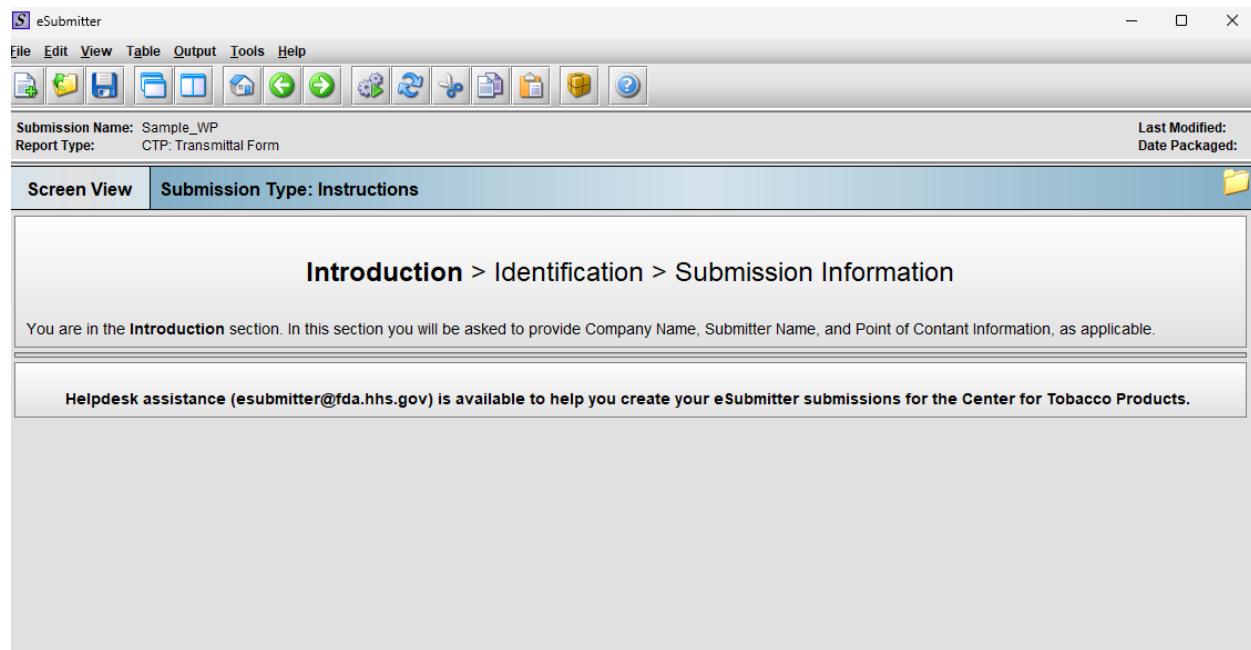
This is a sample submission regarding warning plans for OCE.

Create New Submission... Open Cancel

Once a file name is entered, the introduction overview screen will appear. There is no content to enter on this screen. The user can press an arrow to move to the next page.



The next page is Submission Type Instructions. There is no content to enter on this screen. The user can press an arrow to move to the next page.



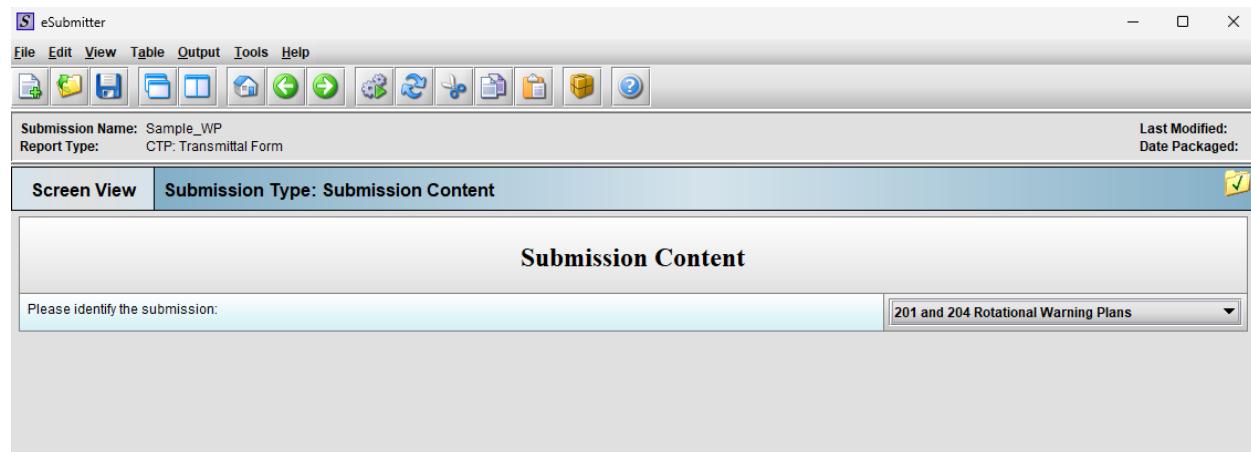
The screenshot shows the eSubmitter software interface. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations. The status bar at the bottom shows "Submission Name: Sample\_WP", "Report Type: CTP: Transmittal Form", "Last Modified:", and "Date Packaged:". The main window has tabs "Screen View" and "Submission Type: Instructions", with "Submission Type: Instructions" selected. The content area displays the following text:

**Introduction > Identification > Submission Information**

You are in the **Introduction** section. In this section you will be asked to provide Company Name, Submitter Name, and Point of Contact information, as applicable.

Helpdesk assistance ([esubmitter@fda.hhs.gov](mailto:esubmitter@fda.hhs.gov)) is available to help you create your eSubmitter submissions for the Center for Tobacco Products.

The next page is Submission Content. Note that this field is optional. There are multiple options in the dropdown including but not limited to Appeals, General Correspondence, Meeting Request, and Rotational Warning Plans. Once selected the user can move to the next page. Note that this field is not required. A blank field will result in an XX submission type on the CTP side.

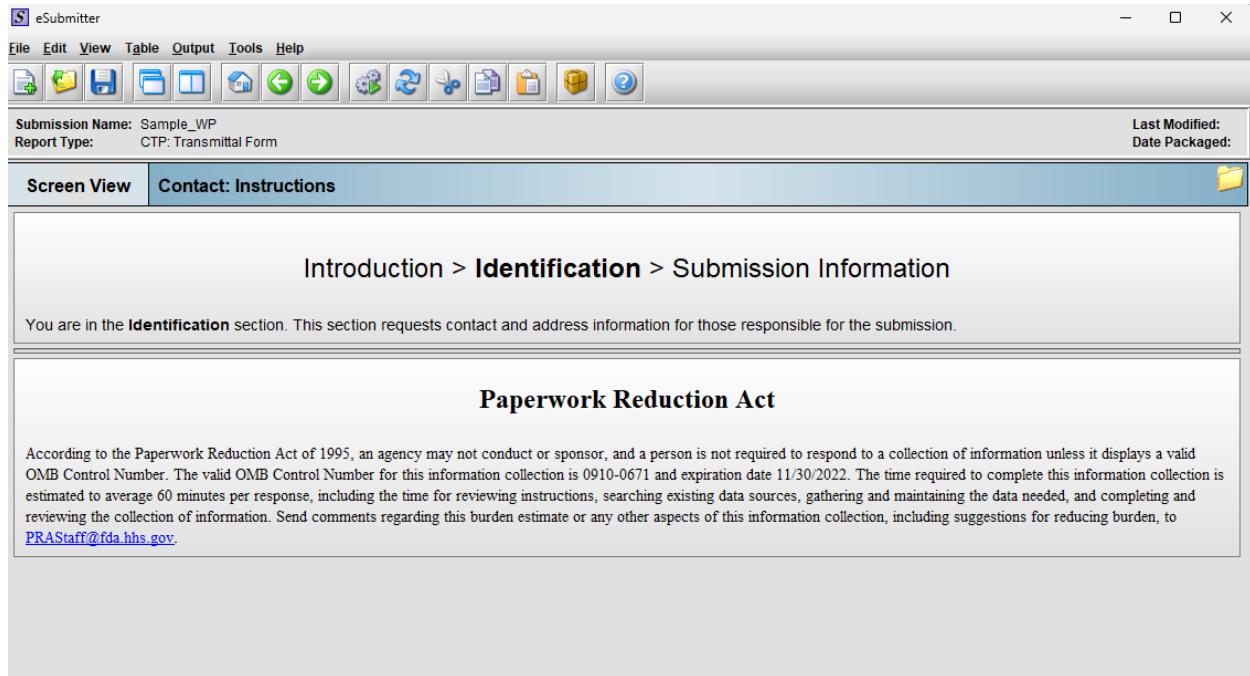


The screenshot shows the eSubmitter software interface. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations. The status bar at the bottom shows "Submission Name: Sample\_WP", "Report Type: CTP: Transmittal Form", "Last Modified:", and "Date Packaged:". The main window has tabs "Screen View" and "Submission Type: Submission Content", with "Submission Type: Submission Content" selected. The content area displays the following text:

**Submission Content**

Please identify the submission:

The next page contains a PRA statement. There is no content to enter on this screen. The user can press an arrow to move to the next page.



The screenshot shows the eSubmitter software interface. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations like Open, Save, Print, and Search. The status bar at the bottom shows "Submission Name: Sample\_WP", "Report Type: CTP: Transmittal Form", "Last Modified:", and "Date Packaged:". The main window has tabs "Screen View" and "Contact: Instructions" (which is selected). The content area displays the following text:

Introduction > **Identification** > Submission Information

You are in the **Identification** section. This section requests contact and address information for those responsible for the submission.

**Paperwork Reduction Act**

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB Control Number for this information collection is 0910-0671 and expiration date 11/30/2022. The time required to complete this information collection is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

The Company contact screen is next. The screen contains several fields to identify the company name, contact name, and other standard contact data entry fields. No field is mandatory on this screen. Users have the option to leave the contact screen blank. Once completed, users can click a button to move forward.

S eSubmitter

File Edit View Table Output Tools Help

Submission Name: Sample\_WP Last Modified:  
Report Type: CTP: Transmittal Form Date Packaged:

**Screen View** **Contact: Company Identification**

Please Identify the Company Type: **Manufacturer**

If Other, please specify:

Please provide the company name and address information below:

**Contact**

|                             |                                   |
|-----------------------------|-----------------------------------|
| Title (e.g., Mr., Ms.):     |                                   |
| First/Given Name:           | Sample                            |
| Middle Name:                |                                   |
| Last Name:                  | Submitter                         |
| Suffix (e.g., Sr, Jr, III): |                                   |
| ➤ Suffix, if Other:         |                                   |
| Degree(s) (e.g., PhD, JD):  |                                   |
| Position Title:             | Sample Submitter                  |
| Email Address:              | samplesubmitter@samplecompany.com |

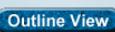
**Address**

|                                     |                 |
|-------------------------------------|-----------------|
| Company Name:                       | Sample Company  |
| Country:                            | United States   |
| Address - Line 1:                   | 123 Main Street |
| Address - Line 2:                   |                 |
| City:                               | Anytown         |
| State:                              | Maryland        |
| State, Province, or Territory Name: |                 |
| Post Office or Zip Code:            | 20903-          |

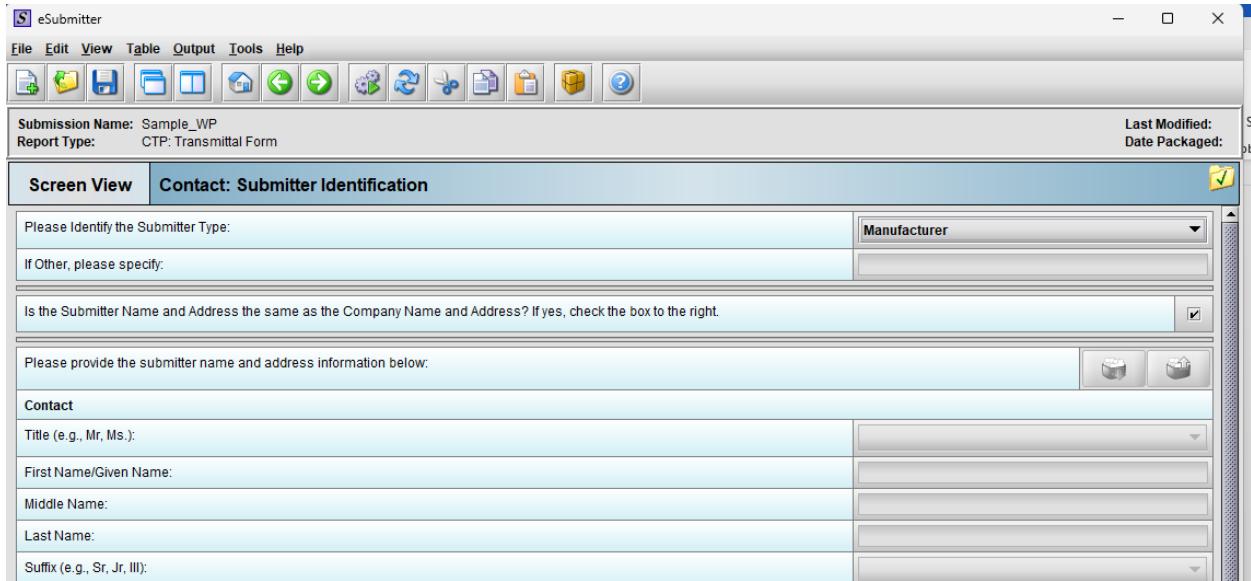
**Phone Numbers**

|                   |  |
|-------------------|--|
| Telephone Number: |  |
|-------------------|--|

Company contact entry continued. Phone Fax and Reference Numbers are at the bottom of the screen. The user can press an arrow to move to the next page. All fields are optional.

|  |  |                |
|--|--|----------------|
| Submission Name:   | Sample_WP  | Last Modified: |
| Report Type:   | CTP: Transmittal Form  | Date Packaged: |
| <b>Screen View</b> <b>Contact: Company Identification</b>   |  |                |
| Position Title:  | Sample Submitter   |                |
| Email Address:   | samplesubmitter@samplecompany.com  |                |
| <b>Address</b>   |  |                |
| Company Name:  | Sample Company   |                |
| Country:   | United States  |                |
| Address - Line 1:  | 123 Main Street  |                |
| Address - Line 2:  |  |                |
| City:  | Anytown  |                |
| State:   | Maryland   |                |
| State, Province, or Territory Name:  |  |                |
| Post Office or Zip Code:   | 20903-   |                |
| <b>Phone Numbers</b>   |  |                |
| Telephone Number:  |  0 of 4 items in the list   |                |
| Telephone Number(s)  |  |                |
| Fax Number:  |  0 of 1 items in the list |                |
| Fax Number(s)  |  |                |
| <b>Reference Numbers</b>   |  |                |
| FDA Established Identifier (FEI):  |  |                |
| D&B D-U-N-S Number:  |  |                |
|    |  |                |

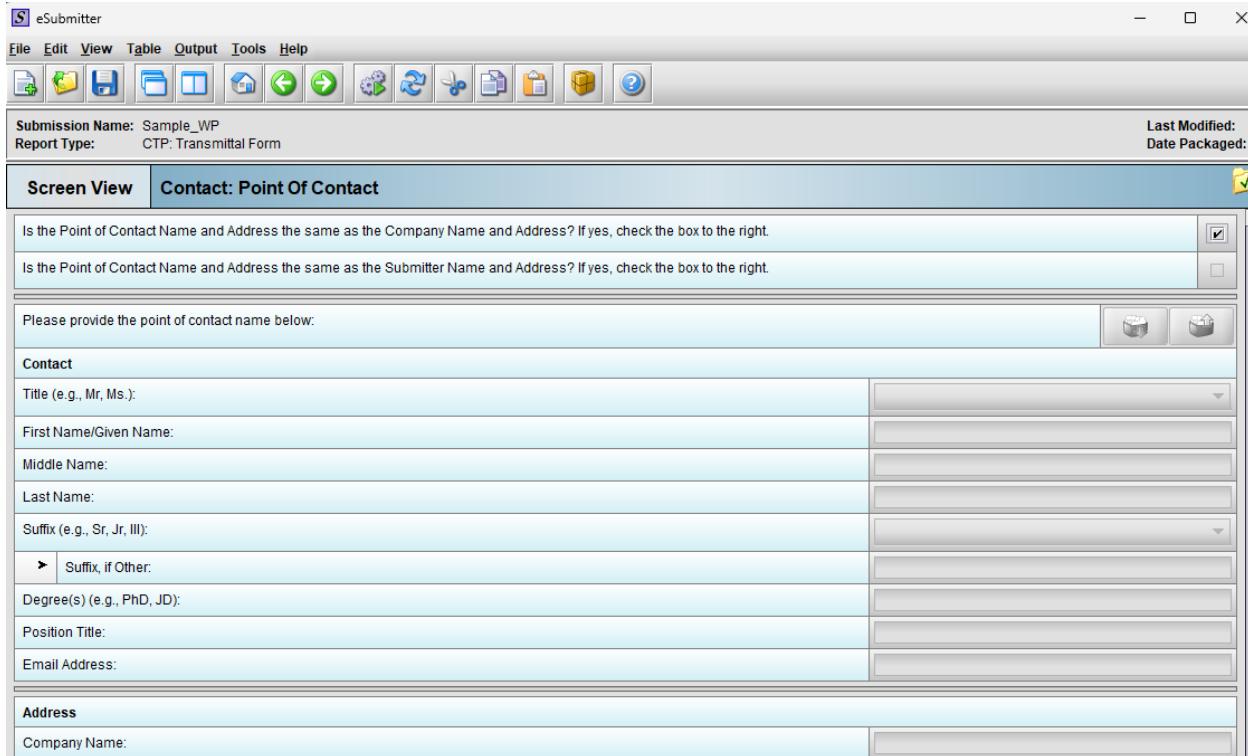
For Contact: Submitter Identification, the fields are the same as contact company. That said, there is an optional checkbox where the user can select if the submitter name is the same as the company name. If selected, the screen will lock and the user can press an arrow to move to the next page. All fields are optional.



The screenshot shows the eSubmitter software interface with the following details:

- Toolbar:** Includes standard file operations (File, Edit, View, Table, Output, Tools, Help) and various icons for file management, search, and data entry.
- Header:** Displays "Submission Name: Sample\_WP" and "Report Type: CTP: Transmittal Form".
- Header:** Shows "Last Modified: Date Packaged:" with a timestamp.
- Tab:** The "Screen View" tab is selected, showing the "Contact: Submitter Identification" screen.
- Form Fields:**
  - "Please Identify the Submitter Type:" dropdown menu is set to "Manufacturer".
  - "If Other, please specify:" text input field.
  - "Is the Submitter Name and Address the same as the Company Name and Address? If yes, check the box to the right." checkbox is checked.
  - "Please provide the submitter name and address information below:" label.
  - Contact:** A table with five rows:
    - Title (e.g., Mr, Ms.):
    - First Name/Given Name:
    - Middle Name:
    - Last Name:
    - Suffix (e.g., Sr, Jr, III):Each row has a text input field and a dropdown arrow.

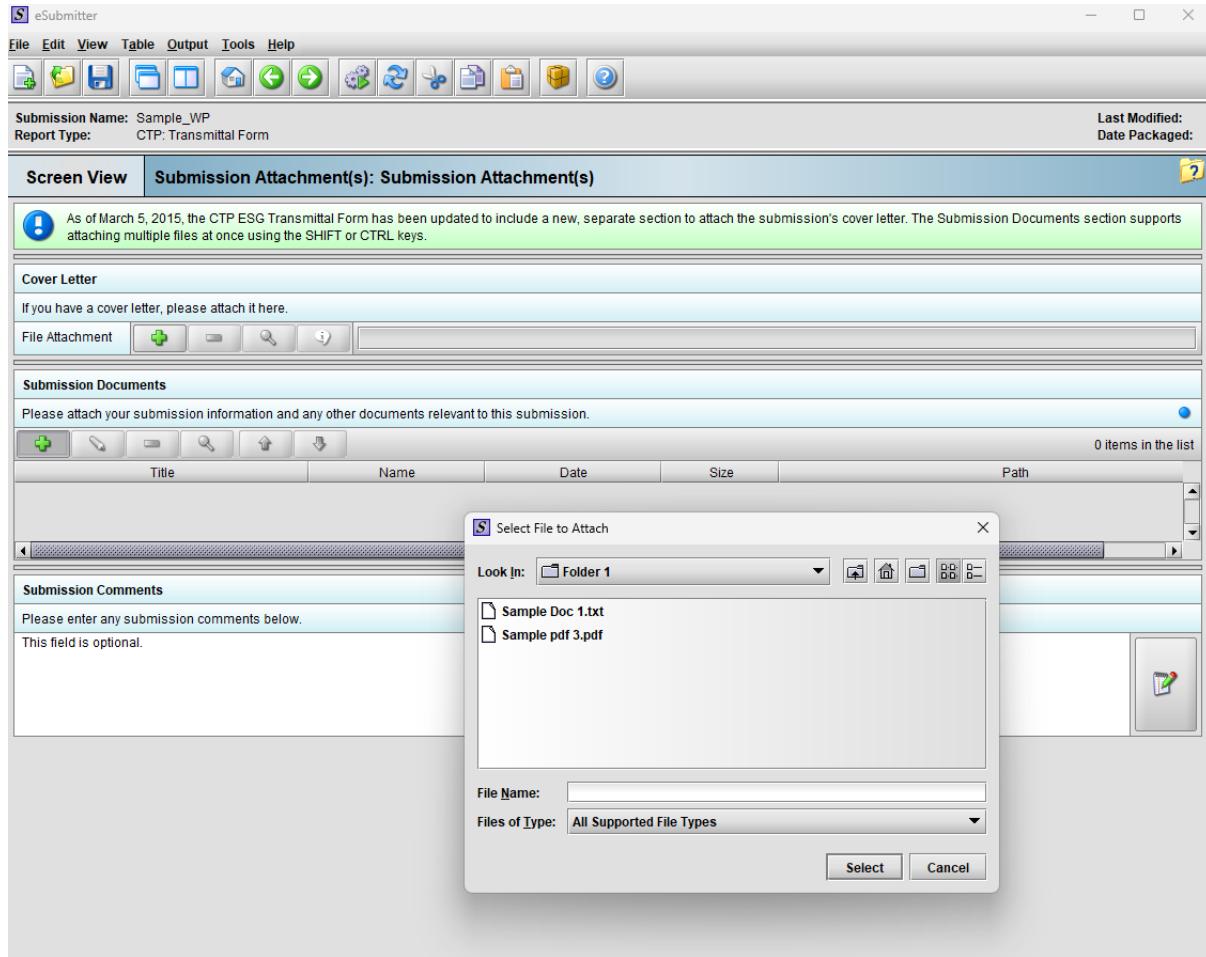
For Contact: POC Identification, the fields are the same as contact company. That said, there are two optional checkboxes where the user can select if the POC name is the same as the company name or the submitter name. If selected, the screen will lock and the user can press an arrow to move to the next page. All fields are optional.



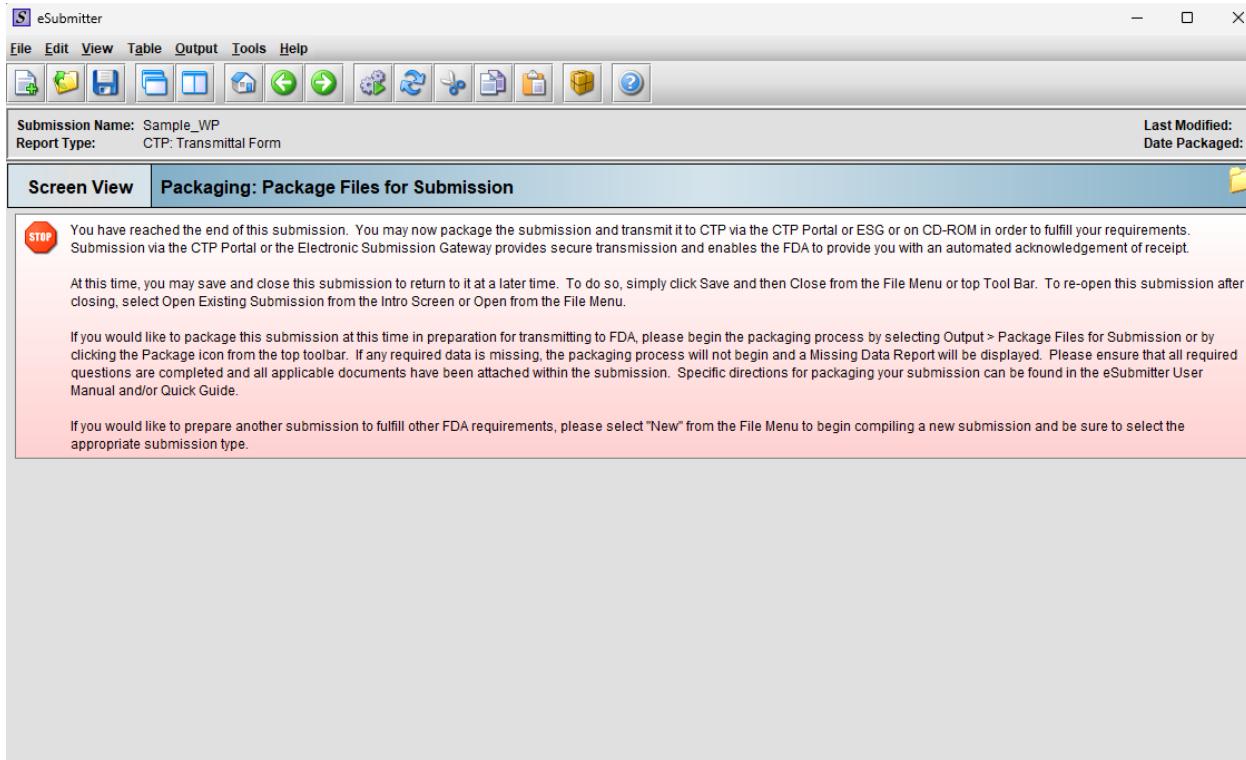
The screenshot shows the eSubmitter software interface with the following details:

- Toolbar:** Includes standard file operations (File, Edit, View, Table, Output, Tools, Help) and specific application icons (e.g., save, open, print, search).
- Header:** Submission Name: Sample\_WP, Report Type: CTP: Transmittal Form, Last Modified: [date], Date Packaged: [date].
- Section Headers:** Screen View, Contact: Point Of Contact.
- Text Fields:** Two checkboxes: "Is the Point of Contact Name and Address the same as the Company Name and Address? If yes, check the box to the right." (checked) and "Is the Point of Contact Name and Address the same as the Submitter Name and Address? If yes, check the box to the right." (unchecked).
- Contact Information:** Fields for Title (e.g., Mr, Ms.), First Name/Given Name, Middle Name, Last Name, Suffix (e.g., Sr, Jr, III), Degree(s) (e.g., PhD, JD), Position Title, and Email Address.
- Address Information:** Company Name field.

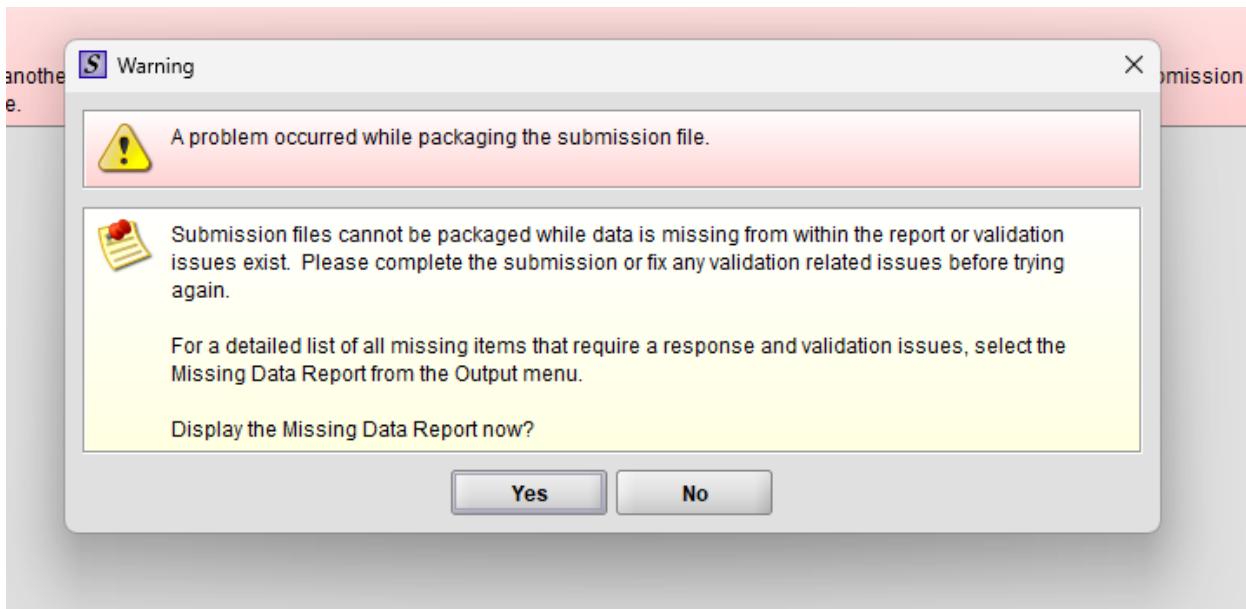
Once all three contacts are entered, the submission attachment screen will pop up. The cover letter and submission comments fields are optional. The submission document field requires at least one document to be uploaded. Multiple documents can be uploaded if the user would like.



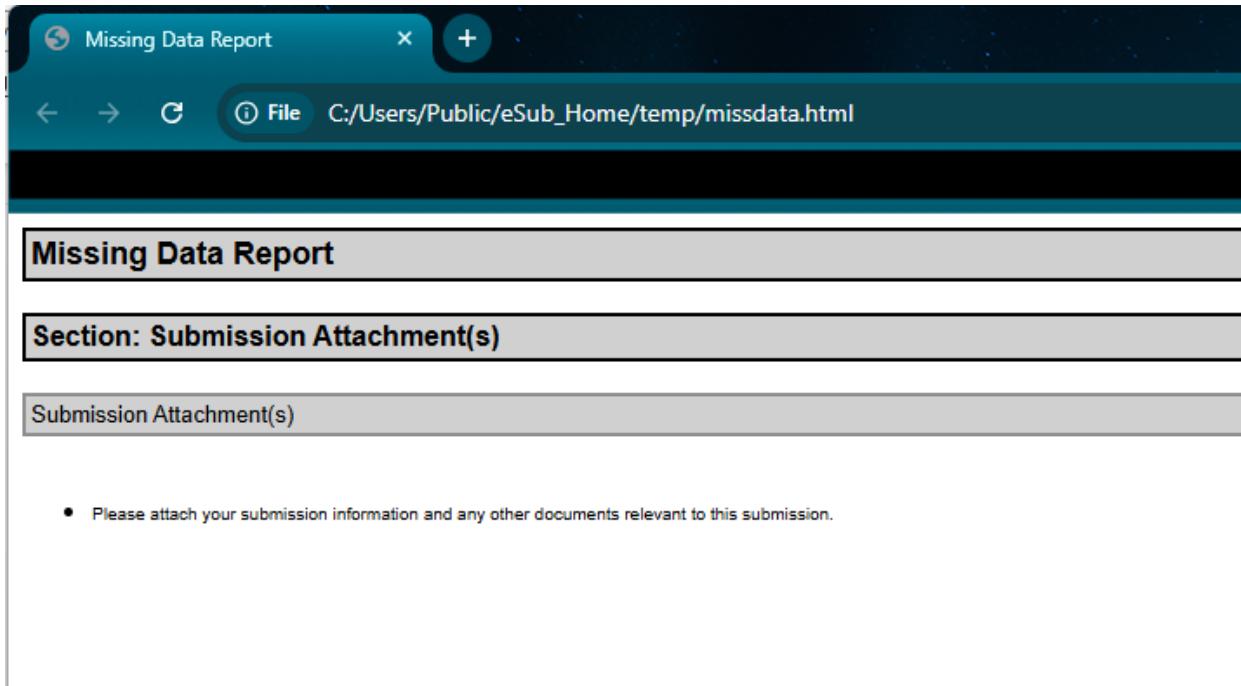
The next page is the end page for data entry. There is no content to enter on this screen. The user will need to select the package button to start packaging the submission. Instructions are available in the box on the screen.



If a mandatory field is missing, a missing data report will be provided. Users can click the yes button to review the missing data report.

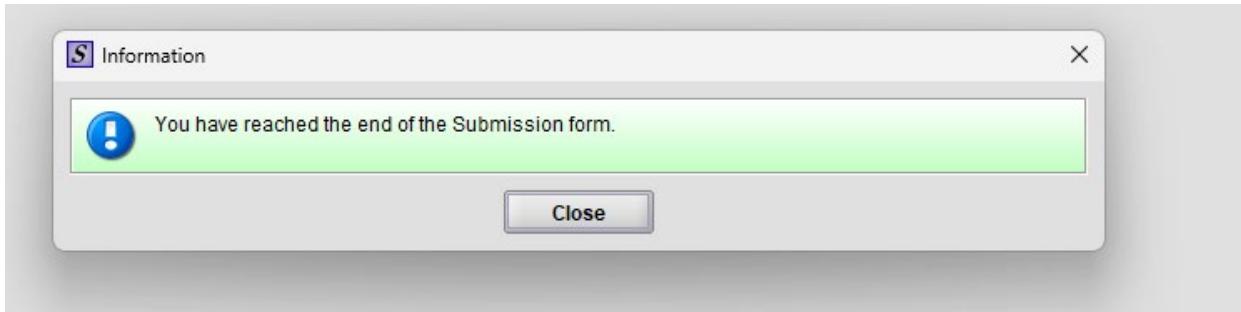


The missing data report will appear as follows:

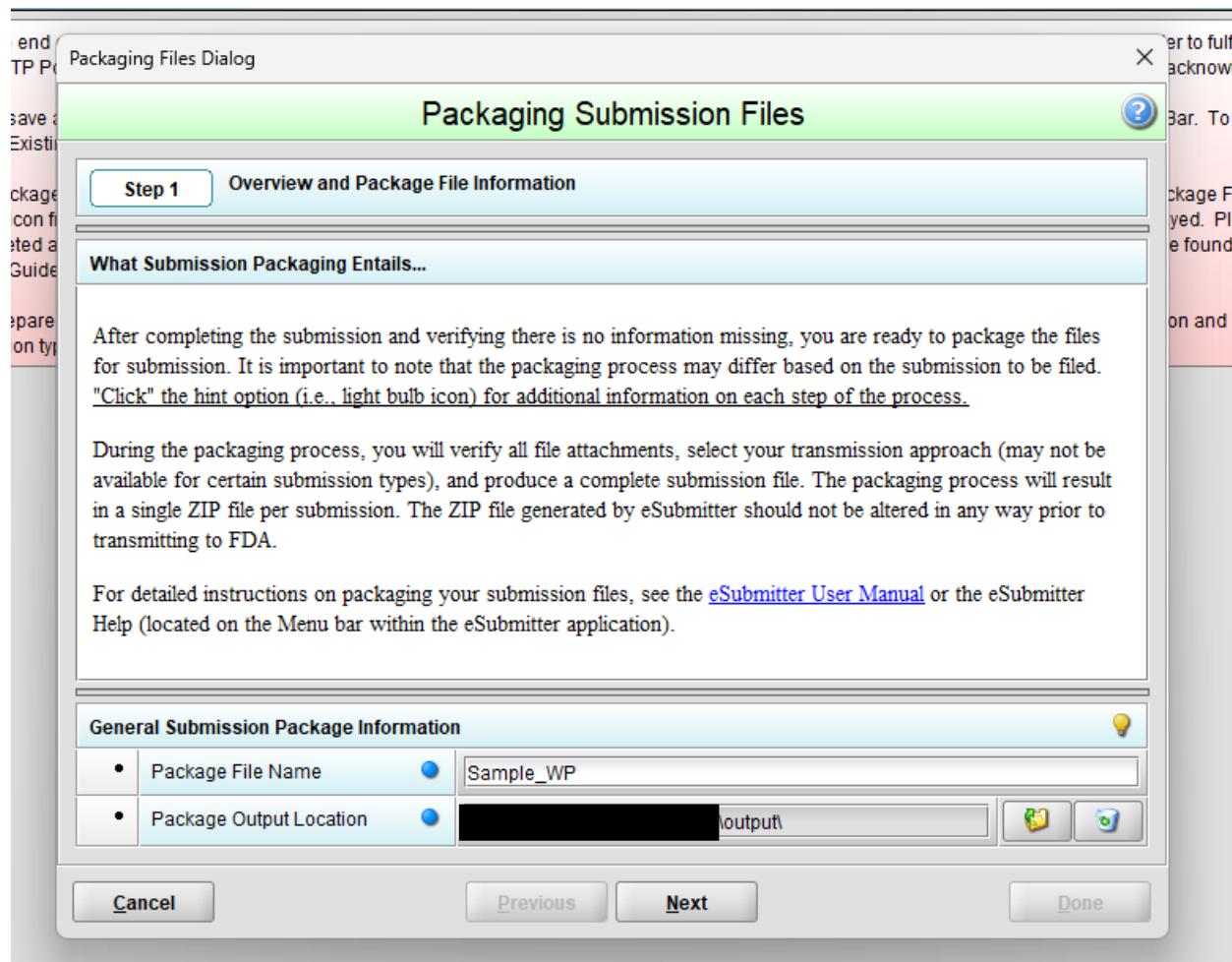


A screenshot of a web browser window titled "Missing Data Report". The address bar shows the file path "C:/Users/Public/eSub\_Home/temp/missdata.html". The main content area displays a "Missing Data Report" page with a section titled "Section: Submission Attachment(s)". Below this, a sub-section titled "Submission Attachment(s)" contains a bullet point: "Please attach your submission information and any other documents relevant to this submission."

If there is no missing data, the following message will display:



The package screens appear as follow. Package File Name and Output location are mandatory. Once input, user will click the next button.



The next page contains a list of all files. There is no content to enter on this screen. The user can press next to move to the next page.

Packaging Files Dialog

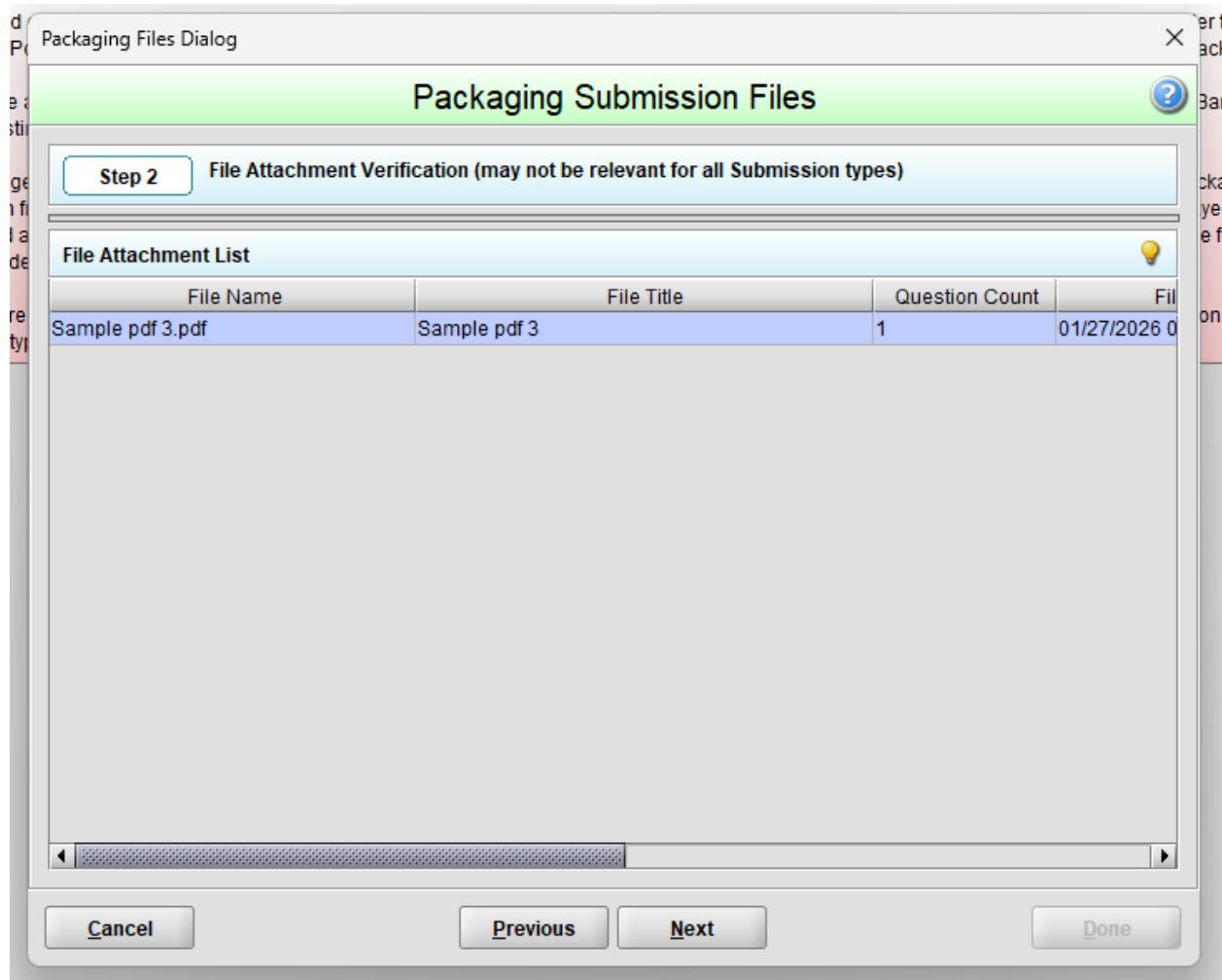
## Packaging Submission Files

Step 2 File Attachment Verification (may not be relevant for all Submission types)

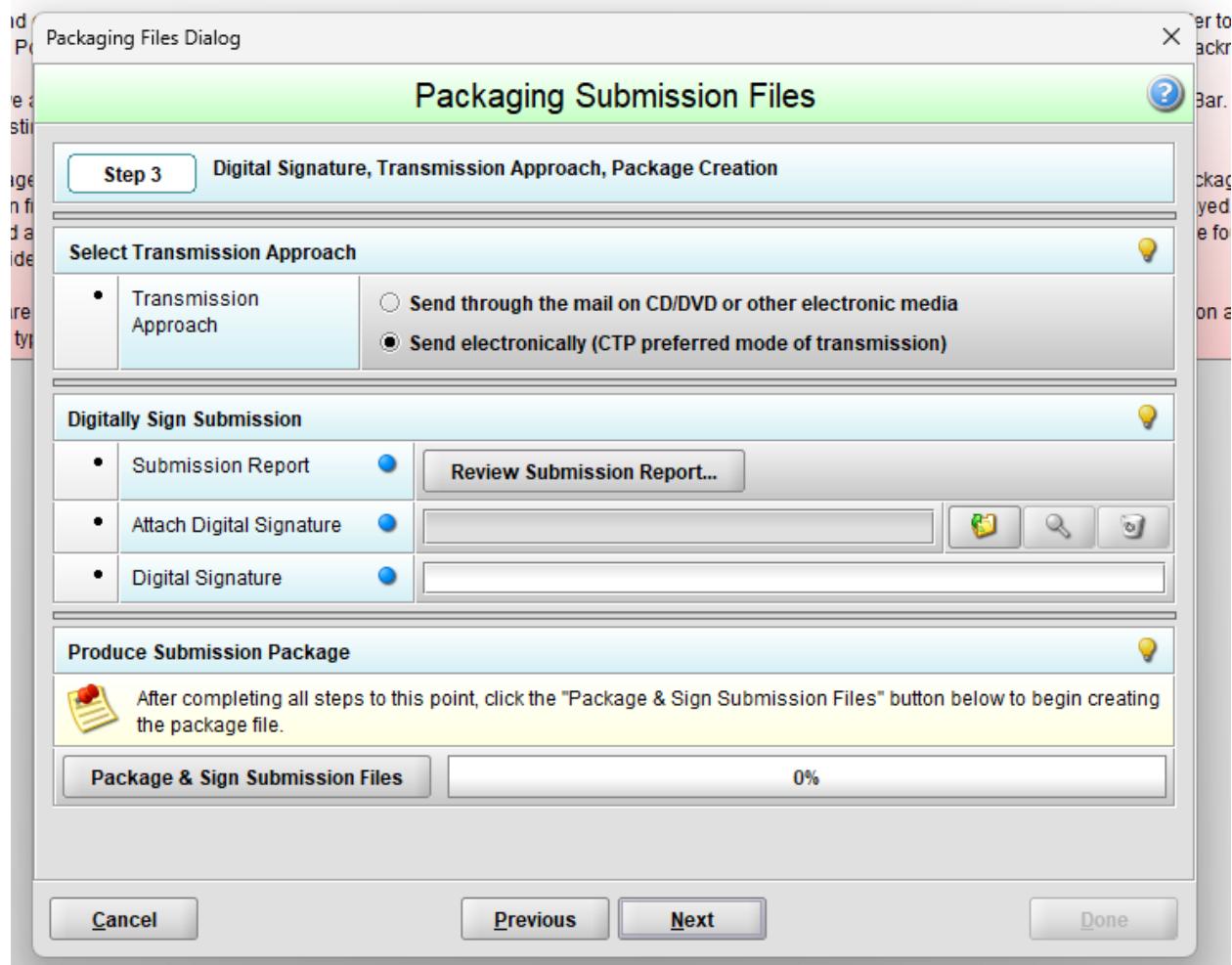
File Attachment List

| File Name        | File Title   | Question Count | File         |
|------------------|--------------|----------------|--------------|
| Sample pdf 3.pdf | Sample pdf 3 | 1              | 01/27/2026 0 |

Cancel Previous Next Done



Step 3 is the final step in eSubmitter. A submission report will be automatically generated and can be reviewed via the submission report button. The digital signature will need to be selected and password input to complete the submission. The digital signature can be generated in Adobe PDF. User will select Package and Sign Submission Files button.



Once packaging is complete, the submission will be located at the output location from Step 1 and be ready for upload into CTP Portal NG.

Packaging Files Dialog

## Packaging Submission Files

Step 3 Digital Signature, Transmission Approach, Package Creation

Select Transmission Approach

- Transmission Approach
- Send through the mail on CD/DVD or other electronic media
- Send electronically (CTP preferred mode of transmission)

Digitally Sign Submission

- Submission Report  Review Submission Report...
- Attach Digital Signature  CTPeSubmissionsHelpDesk.pfx 
- Digital Signature  \*\*\*\*\*

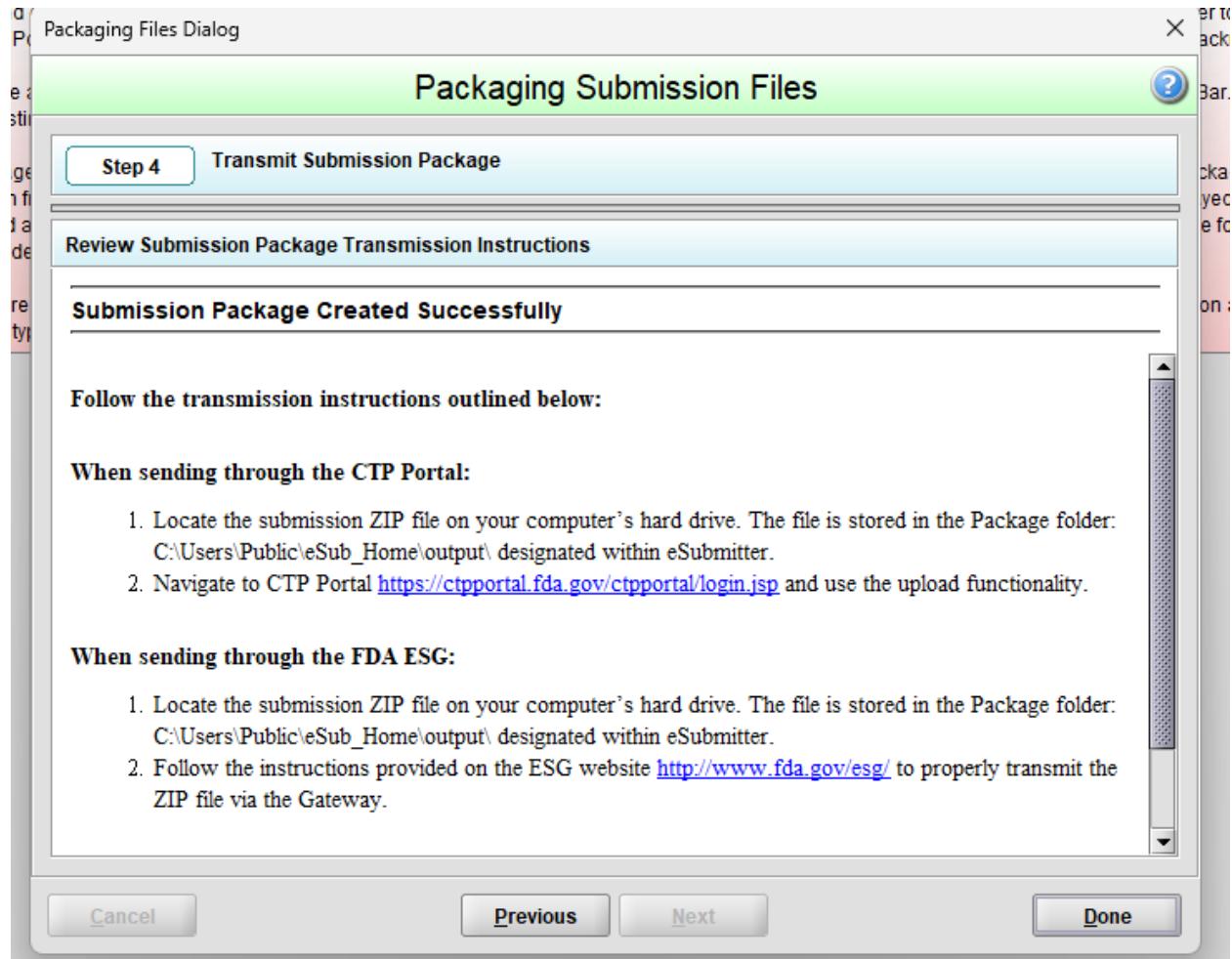
Produce Submission Package

 After completing all steps to this point, click the "Package & Sign Submission Files" button below to begin creating the package file.

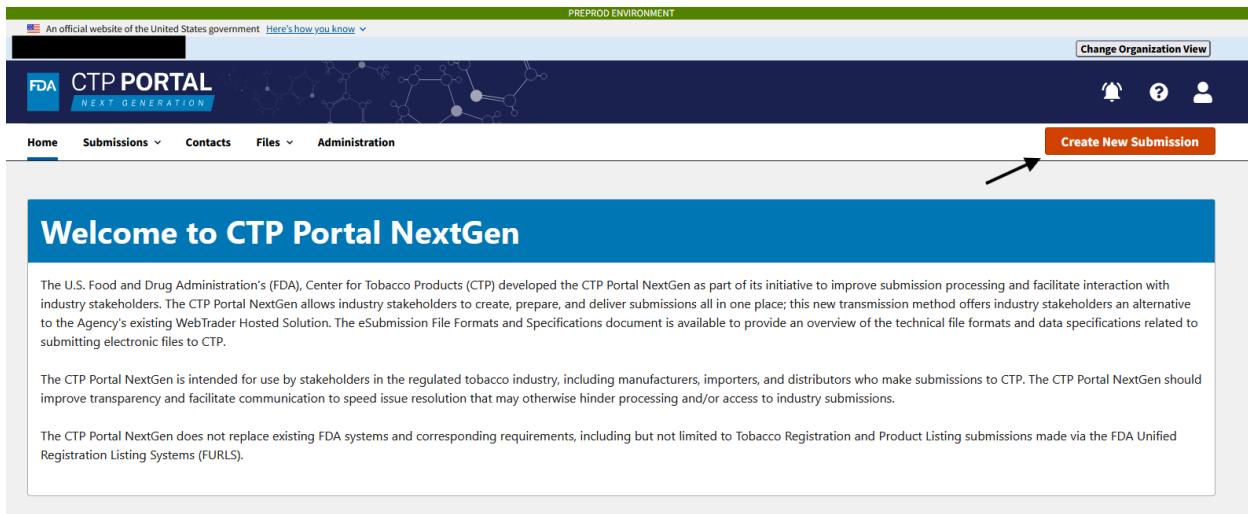
Package & Sign Submission Files Complete.

[Cancel](#) [Previous](#) [Next](#) [Done](#)

The next page contains information on how to submit. There is no content to enter on this screen. The user can press next to move to the next page.



In CTP Portal, once the user logs in, the user will select Create New Submission.



PREPROD ENVIRONMENT

An official website of the United States government [Here's how you know](#)

**FDA CTP PORTAL** NEXT GENERATION

Home Submissions Contacts Files Administration

Create New Submission

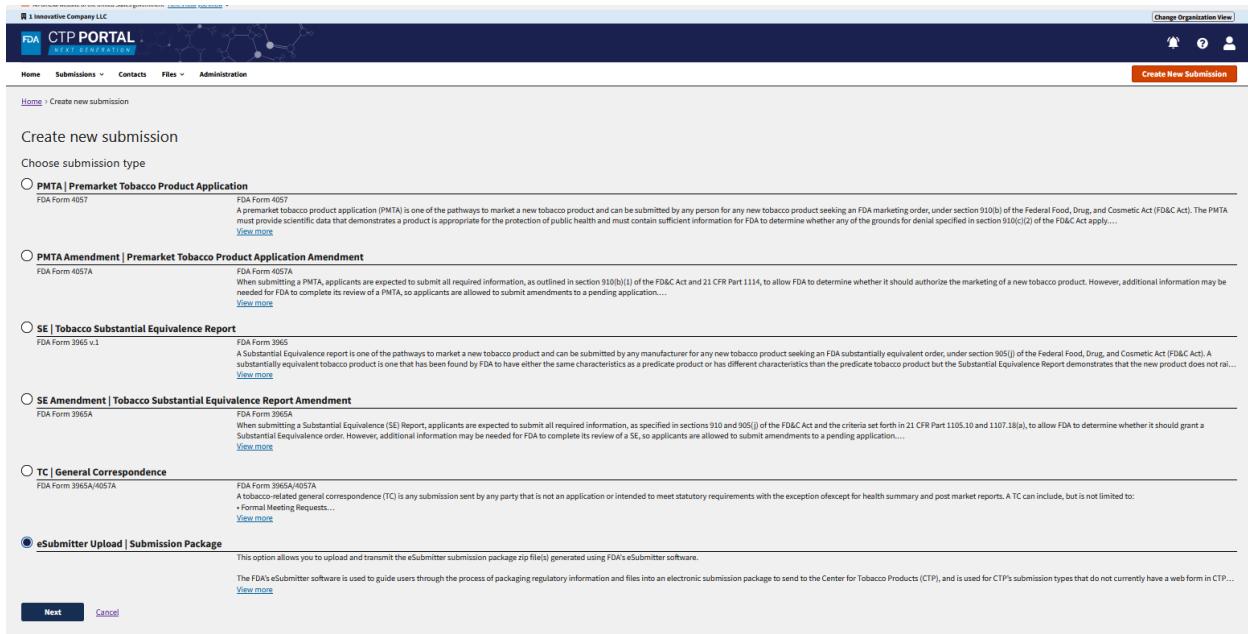
## Welcome to CTP Portal NextGen

The U.S. Food and Drug Administration's (FDA), Center for Tobacco Products (CTP) developed the CTP Portal NextGen as part of its initiative to improve submission processing and facilitate interaction with industry stakeholders. The CTP Portal NextGen allows industry stakeholders to create, prepare, and deliver submissions all in one place; this new transmission method offers industry stakeholders an alternative to the Agency's existing WebTrader Hosted Solution. The eSubmission File Formats and Specifications document is available to provide an overview of the technical file formats and data specifications related to submitting electronic files to CTP.

The CTP Portal NextGen is intended for use by stakeholders in the regulated tobacco industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal NextGen should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

The CTP Portal NextGen does not replace existing FDA systems and corresponding requirements, including but not limited to Tobacco Registration and Product Listing submissions made via the FDA Unified Registration Listing Systems (FURLS).

User will select eSubmitter Upload.



Home Submissions Contacts Files Administration

[Home](#) > Create new submission

### Create new submission

Choose submission type

**PMTA | Premarket Tobacco Product Application**

FDA Form 4057  
A premarket tobacco product application (PMTA) is one of the pathways to market a new tobacco product and can be submitted by any person for any new tobacco product seeking an FDA marketing order, under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The PMTA must provide scientific data that demonstrates a product is appropriate for the protection of public health and must contain sufficient information for FDA to determine whether any of the grounds for denial specified in section 910(c)(2) of the FD&C Act apply....  
[View more](#)

**PMTA Amendment | Premarket Tobacco Product Application Amendment**

FDA Form 4057A  
When submitting a PMTA, applicants are expected to submit all required information, as outlined in section 910(b)(1) of the FD&C Act and 21 CFR Part 1114, to allow FDA to determine whether it should authorize the marketing of a new tobacco product. However, additional information may be needed for FDA to complete its review of a PMTA, so applicants are allowed to submit amendments to a pending application....  
[View more](#)

**SE | Tobacco Substantial Equivalence Report**

FDA Form 3965 v.1  
FDA Form 3965  
A Substantial Equivalence report is one of the pathways to market a new tobacco product and can be submitted by any manufacturer for any new tobacco product seeking an FDA substantially equivalent order, under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A substantially equivalent tobacco product is one that has been found by FDA to have either the same characteristics as a predicate product or has different characteristics than the predicate tobacco product but the Substantial Equivalence Report demonstrates that the new product does not raise significant risk....  
[View more](#)

**SE Amendment | Tobacco Substantial Equivalence Report Amendment**

FDA Form 3965A  
FDA Form 3965A  
When submitting a Substantial Equivalence (SE) Report, applicants are expected to submit all required information, as specified in sections 910 and 905(j) of the FD&C Act and the criteria set forth in 21 CFR Part 1105.10 and 1107.18(a), to allow FDA to determine whether it should grant a Substantial Equivalence order. However, additional information may be needed for FDA to complete its review of a SE, so applicants are allowed to submit amendments to a pending application....  
[View more](#)

**TC | General Correspondence**

FDA Form 3965A/4057A  
FDA Form 3965A/4057A  
A tobacco-related general correspondence (TC) is any submission sent by any party that is not an application or intended to meet statutory requirements with the exception of except for health summary and post market reports. A TC can include, but is not limited to:

- Formal Meeting Requests...

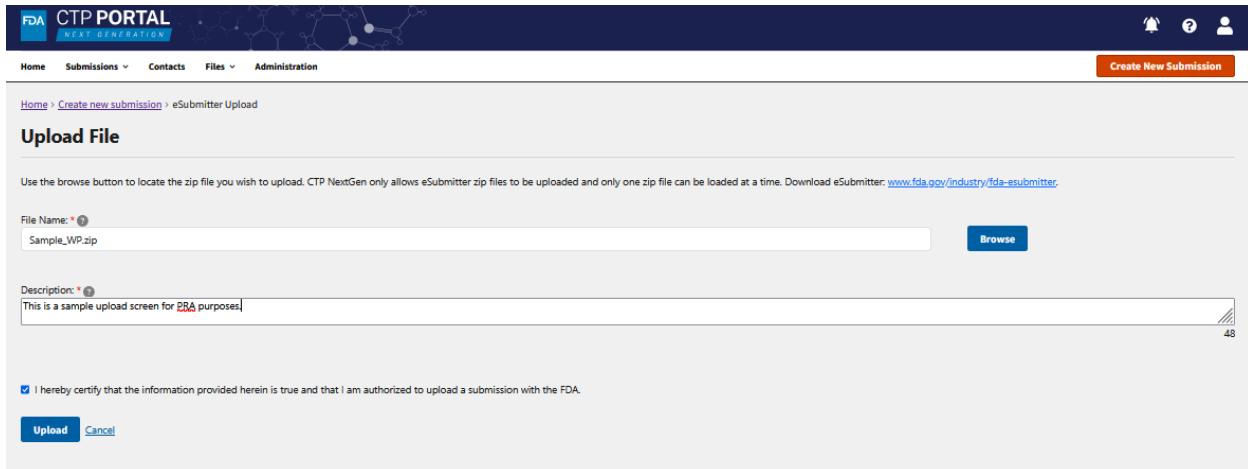
  
[View more](#)

**eSubmitter Upload | Submission Package**

This option allows you to upload and transmit the eSubmitter submission package zip file(s) generated using FDA's eSubmitter software.  
The FDA's eSubmitter software is used to guide users through the process of packaging regulatory information and files into an electronic submission package to send to the Center for Tobacco Products (CTP), and is used for CTP's submission types that do not currently have a web form in CTP....  
[View more](#)

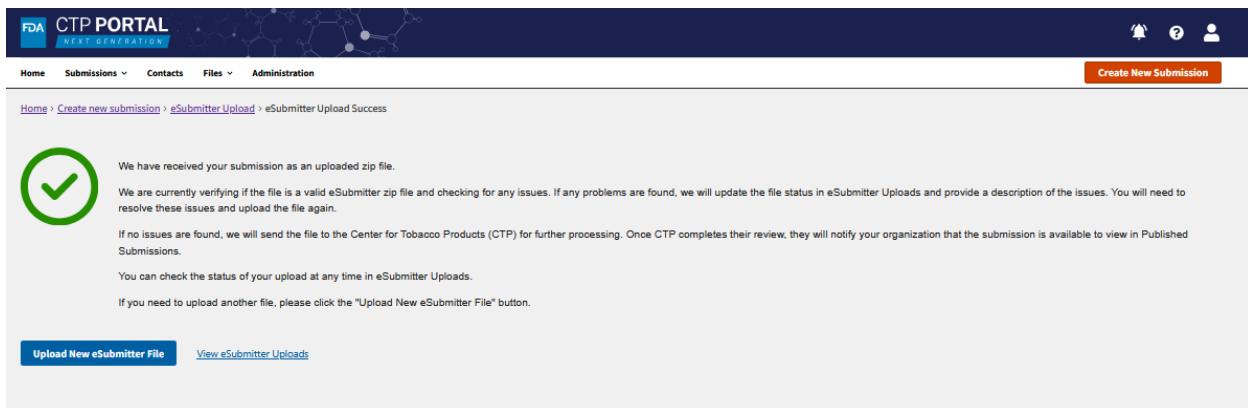
**Next** **Cancel**

The user will browse to and select the eSubmitter file.



The screenshot shows the FDA CTP PORTAL Next Generation interface. The top navigation bar includes links for Home, Submissions, Contacts, Files, and Administration, along with a 'Create New Submission' button and user profile icons. The main content area is titled 'Upload File'. It contains a file input field with 'Sample\_WP.zip' selected, a 'Browse' button, and a 'Description' text area containing the placeholder text 'This is a sample upload screen for PMA purposes.' A checkbox for a certification statement is present, and at the bottom are 'Upload' and 'Cancel' buttons.

Once you click the upload button, a loading screen will appear then be replaced by the upload complete screen. At this point, if no errors are found, the submission will transmit to CTP and the industry user has completed their submission.



The screenshot shows the FDA CTP PORTAL Next Generation interface after a successful upload. The top navigation bar and main menu are identical to the previous screenshot. The main content area is titled 'eSubmitter Upload Success'. It features a green circular icon with a checkmark. The message text reads: 'We have received your submission as an uploaded zip file. We are currently verifying if the file is a valid eSubmitter zip file and checking for any issues. If any problems are found, we will update the file status in eSubmitter Uploads and provide a description of the issues. You will need to resolve these issues and upload the file again. If no issues are found, we will send the file to the Center for Tobacco Products (CTP) for further processing. Once CTP completes their review, they will notify your organization that the submission is available to view in Published Submissions. You can check the status of your upload at any time in eSubmitter Uploads. If you need to upload another file, please click the "Upload New eSubmitter File" button.' At the bottom are 'Upload New eSubmitter File' and 'View eSubmitter Uploads' buttons.