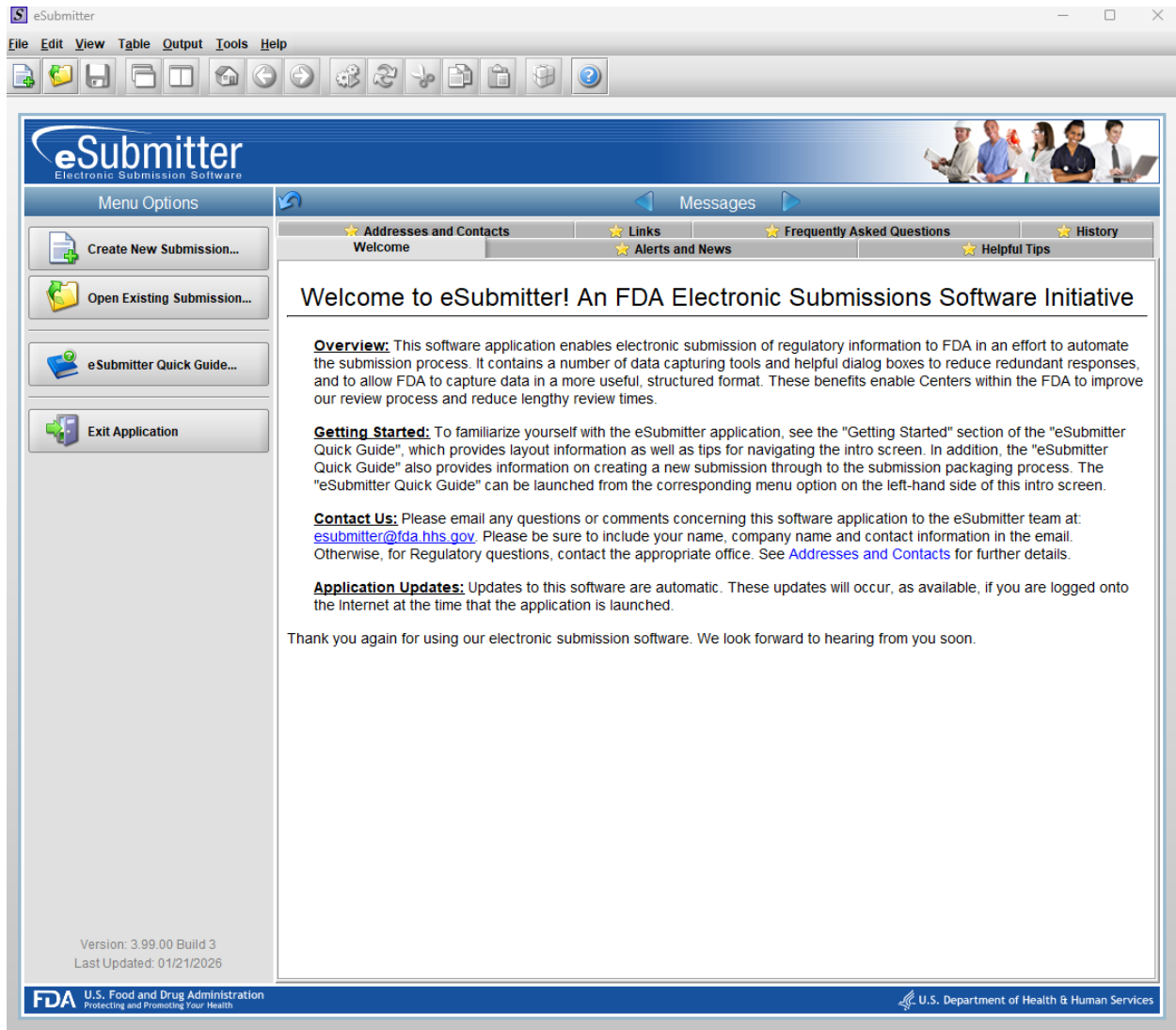
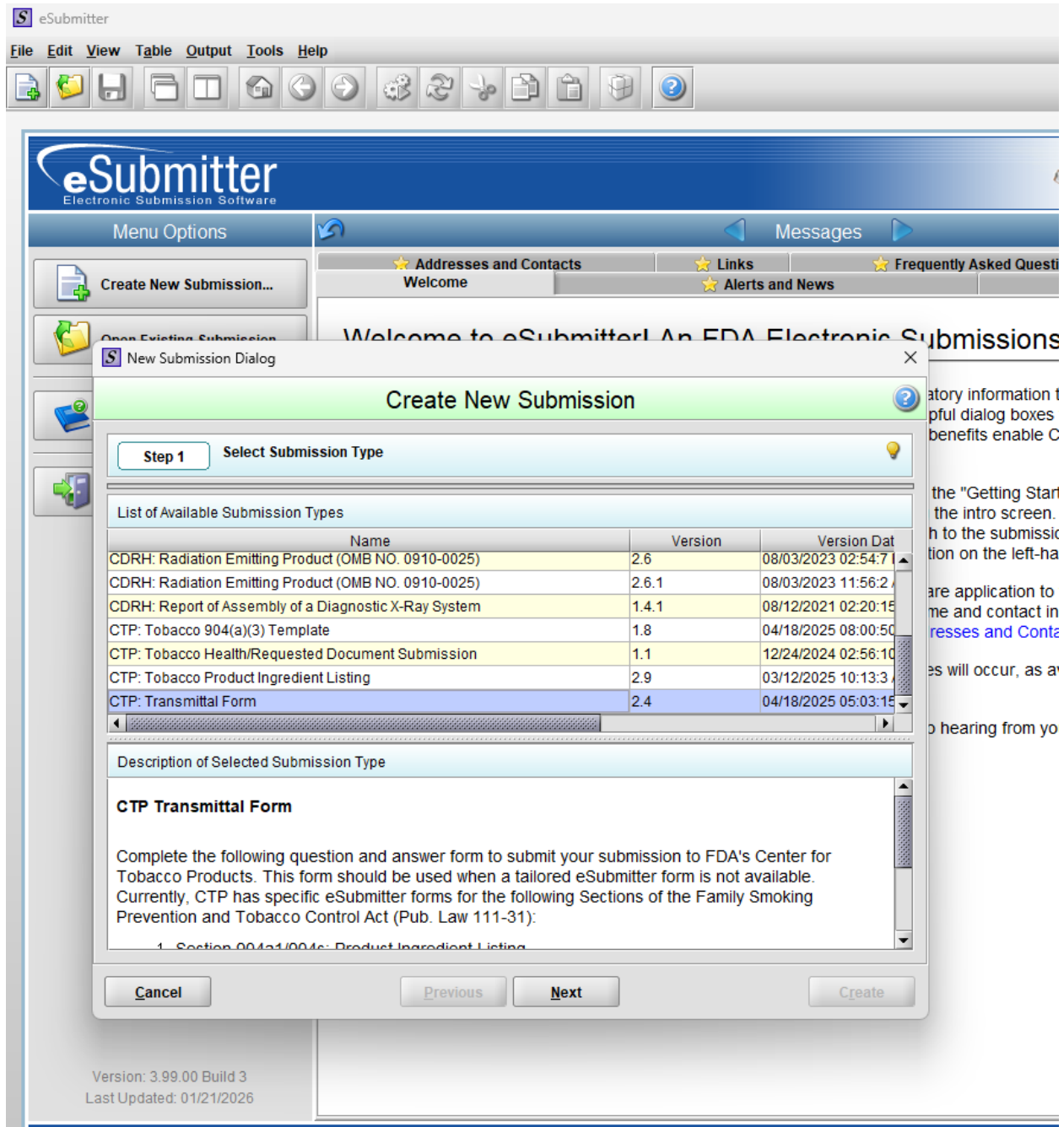


Steps to submit a new Warning Plan:

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.


New Submission Dialog

Create New Submission

Step 2 Provide Submission Details

Specify the Submission Descriptive and File Names

- Descriptive Name  Sample_WP
- File Name (.xml)  Sample_WP

Additional Comments about this Submission 

This field is optional.

This is a sample submission regarding warning plans for OCE.

Cancel Previous Next **C**reate

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

Open Submission Dialog

Open Existing Submission

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

Submission Name (a)
Sample_WP

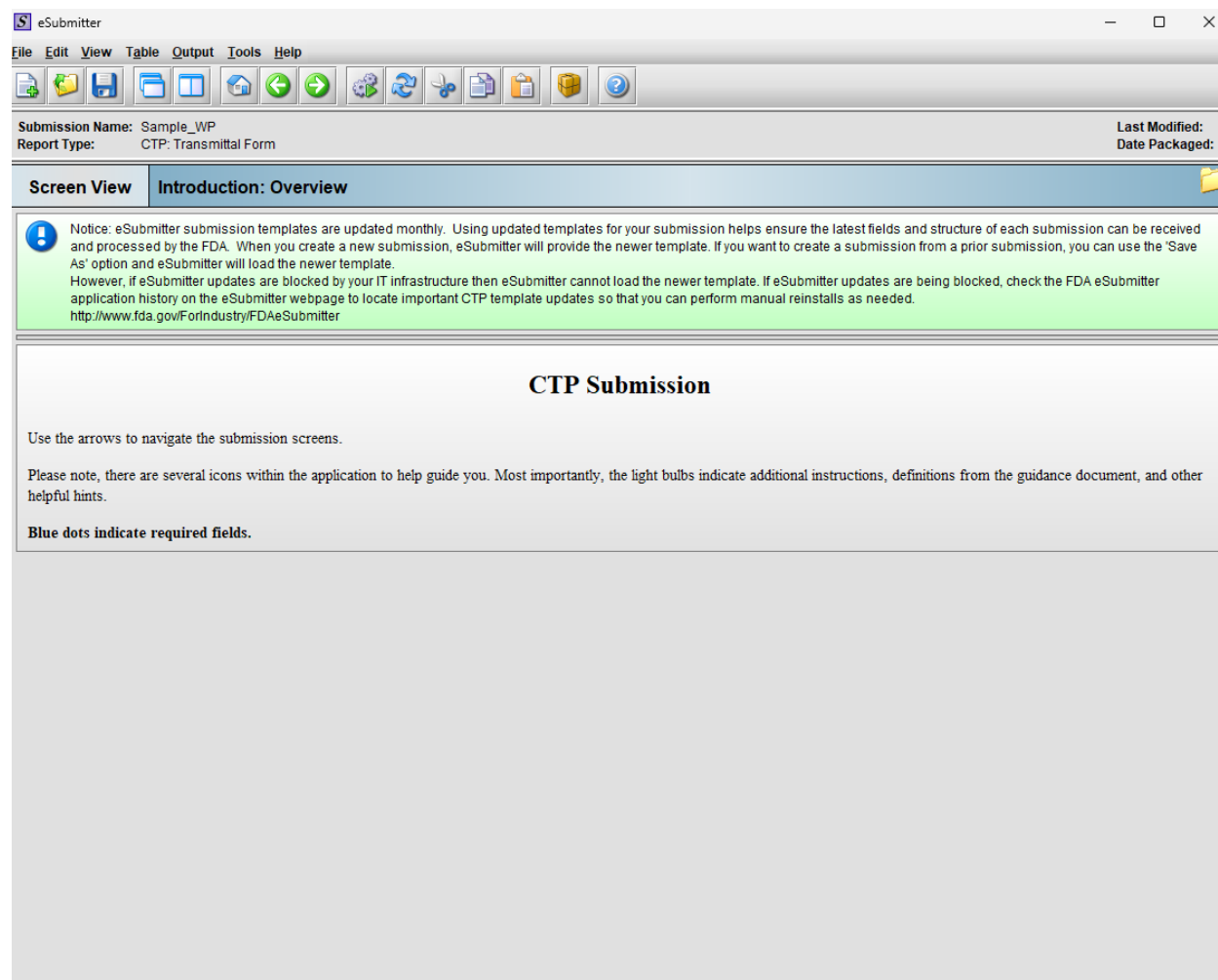
View the Description of the Selected Submission

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 application window. 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 and navigation. The status bar at the top indicates "Submission Name: Sample_WP" and "Report Type: CTP: Transmittal Form". On the right, it shows "Last Modified:" and "Date Packaged:". The main content area has a tab labeled "Submission Type: Instructions". Below the tab, the text reads "Introduction > Identification > Submission Information". A message states: "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." At the bottom, a helpdesk assistance message is displayed: "Helpdesk assistance (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 application window with the "Submission Type: Submission Content" tab selected. The main content area is titled "Submission Content". Below the title, there is a text input field labeled "Please identify the submission:". To the right of this field is a dropdown menu currently displaying "201 and 204 Rotational Warning Plans". The status bar at the top remains the same as in the previous screenshot.

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 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains icons for file operations (new, open, save, print, etc.) and navigation (back, forward, home, etc.). The status bar at the top right shows "Last Modified:" and "Date Packaged:". Below the status bar, there are two tabs: "Screen View" and "Contact: Instructions", with "Contact: Instructions" being the active tab. The main content area displays a breadcrumb trail: "Introduction > **Identification** > Submission Information". Below this, a message states: "You are in the **Identification** section. This section requests contact and address information for those responsible for the submission." The next section is titled "Paperwork Reduction Act" and contains a paragraph of text explaining the act and providing a link to "PRASStaff@fda.hhs.gov".

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Sample_WP
Report Type: CTP: Transmittal Form

Last Modified:
Date Packaged:

Screen View Contact: Instructions

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 PRASStaff@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.

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Sample_WP
Report Type: CTP: Transmittal Form

Last Modified:
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:



Screen View	Contact: Company Identification	
--------------------	--	---

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:	
    	
0 of 4 items in the list	
Telephone Number(s)	
Fax Number:	
    	
0 of 1 items in the list	
Fax Number(s)	

Reference Numbers	
FDA Established Identifier (FEI):	
D&B D-U-N-S Number:	

	Outline View	
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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' application window. The title bar includes the application name and standard window controls. The menu bar contains 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar features icons for file operations (open, save, print, etc.) and navigation (back, forward, home, etc.).

Below the toolbar, a status bar displays 'Submission Name: Sample_WP' and 'Report Type: CTP: Transmittal Form'. On the right side of this bar, it shows 'Last Modified:' and 'Date Packaged:'.

The main content area has a tabbed interface. The 'Screen View' tab is active, showing the 'Contact: Submitter Identification' form. The form includes the following sections:

- Submitter Type:** A dropdown menu currently set to 'Manufacturer'. Below it is a text field labeled 'If Other, please specify:'.
- Confirmation:** A checkbox labeled 'Is the Submitter Name and Address the same as the Company Name and Address? If yes, check the box to the right.' The checkbox is checked.
- Submitter Information:** A section titled 'Please provide the submitter name and address information below:' with two printer icons to its right.
- Contact Fields:** A section titled 'Contact' containing five text input fields: 'Title (e.g., Mr, Ms.):', 'First Name/Given Name:', 'Middle Name:', 'Last Name:', and 'Suffix (e.g., Sr, Jr, III):'.

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.

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Sample_WP
Report Type: CTP: Transmittal Form

Last Modified:
Date Packaged:

Screen View **Contact: Point Of Contact**

Is the Point of Contact Name and Address the same as the Company Name and Address? If yes, check the box to the right. ☒

Is the Point of Contact Name and Address the same as the Submitter Name and Address? If yes, check the box to the right. ☐

Please provide the point of contact name below:

Contact

Title (e.g., Mr, Ms.):

First Name/Given Name:

Middle Name:

Last Name:

Suffix (e.g., Sr, Jr, III):

► Suffix, if Other:

Degree(s) (e.g., PhD, JD):

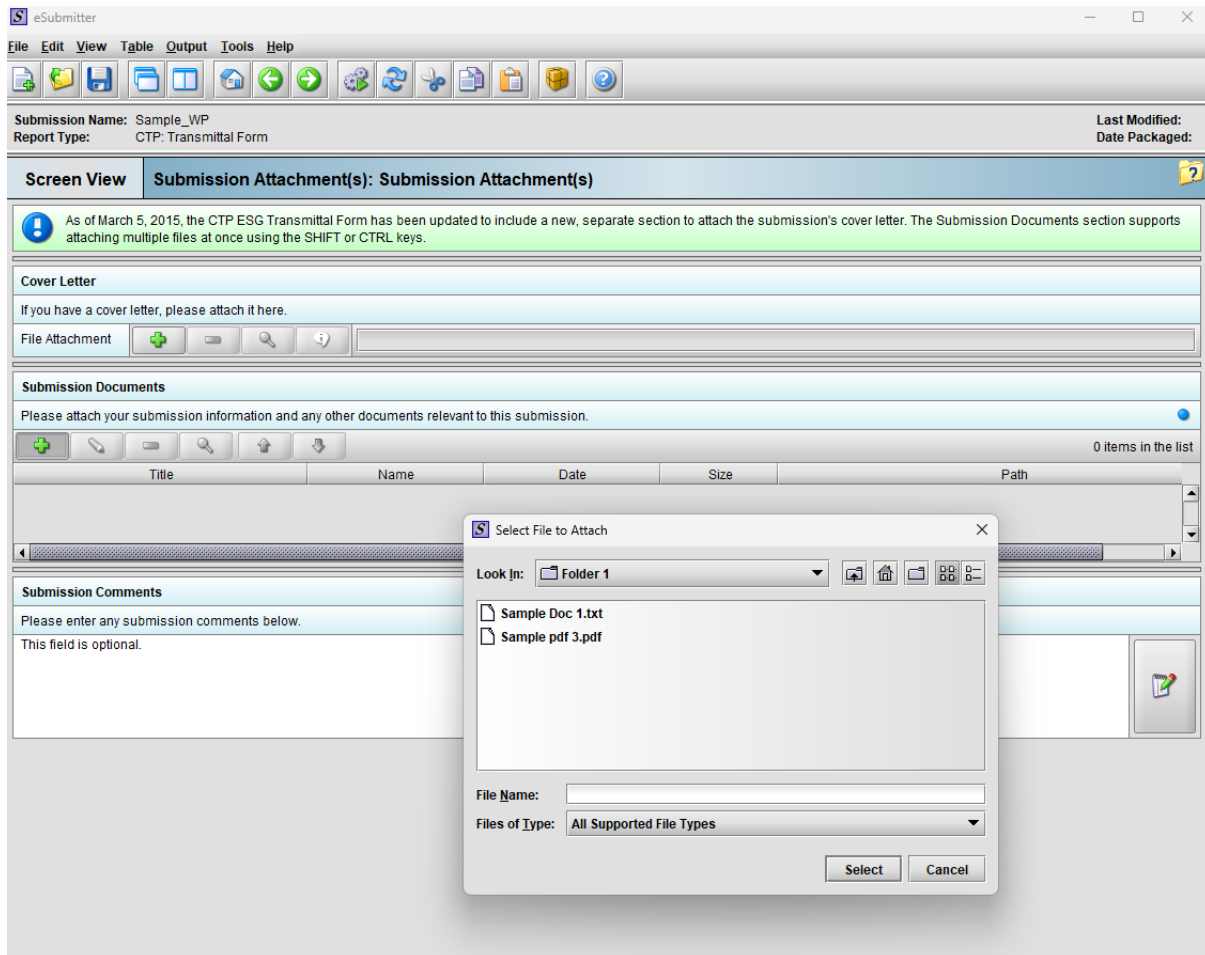
Position Title:

Email Address:

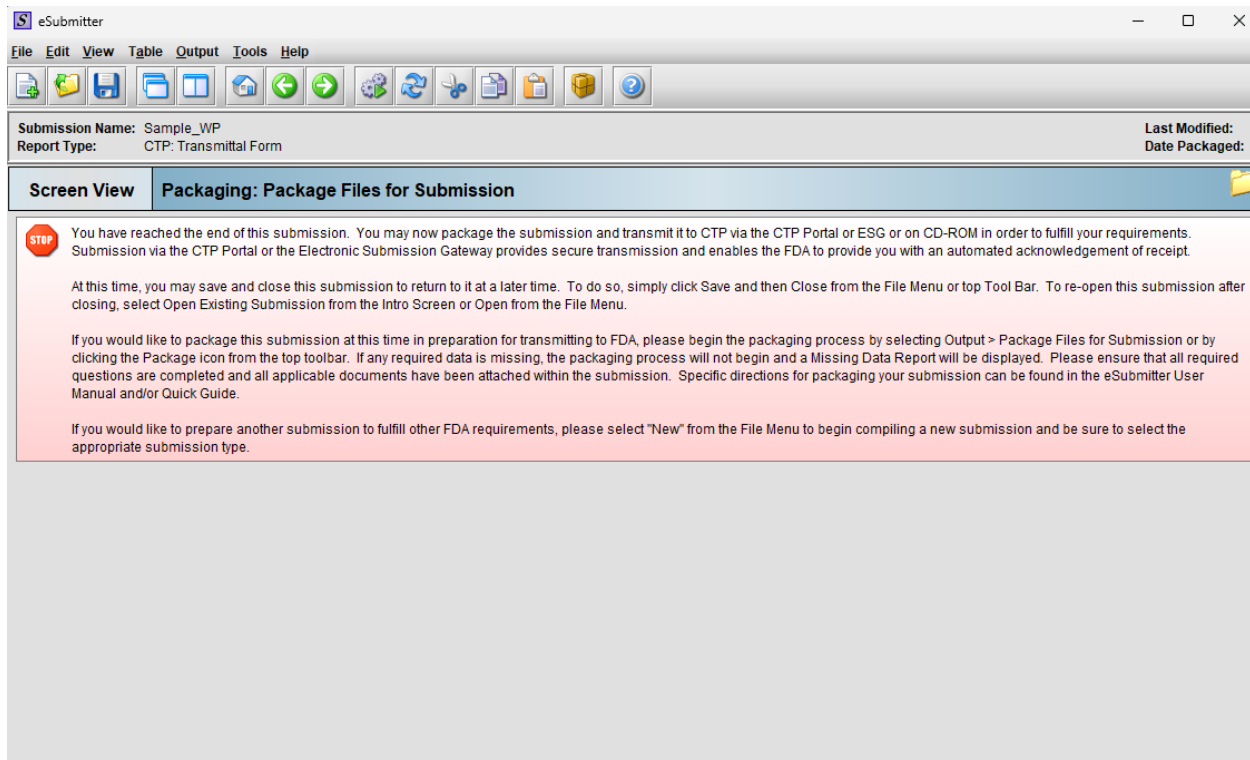
Address

Company Name:

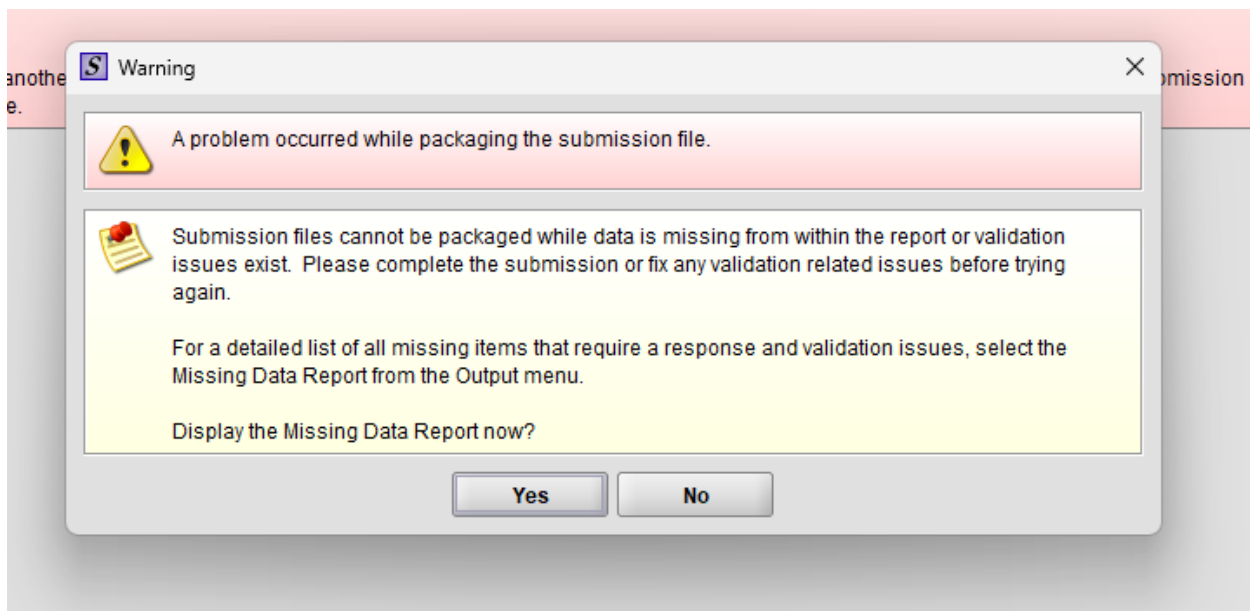
Once all three contacts are entered, the submission attachment screen will pop up. The cover letter and submission comments fields are optional. The submission document field requires at least one document to be uploaded. Multiple documents can be uploaded if the user would like.



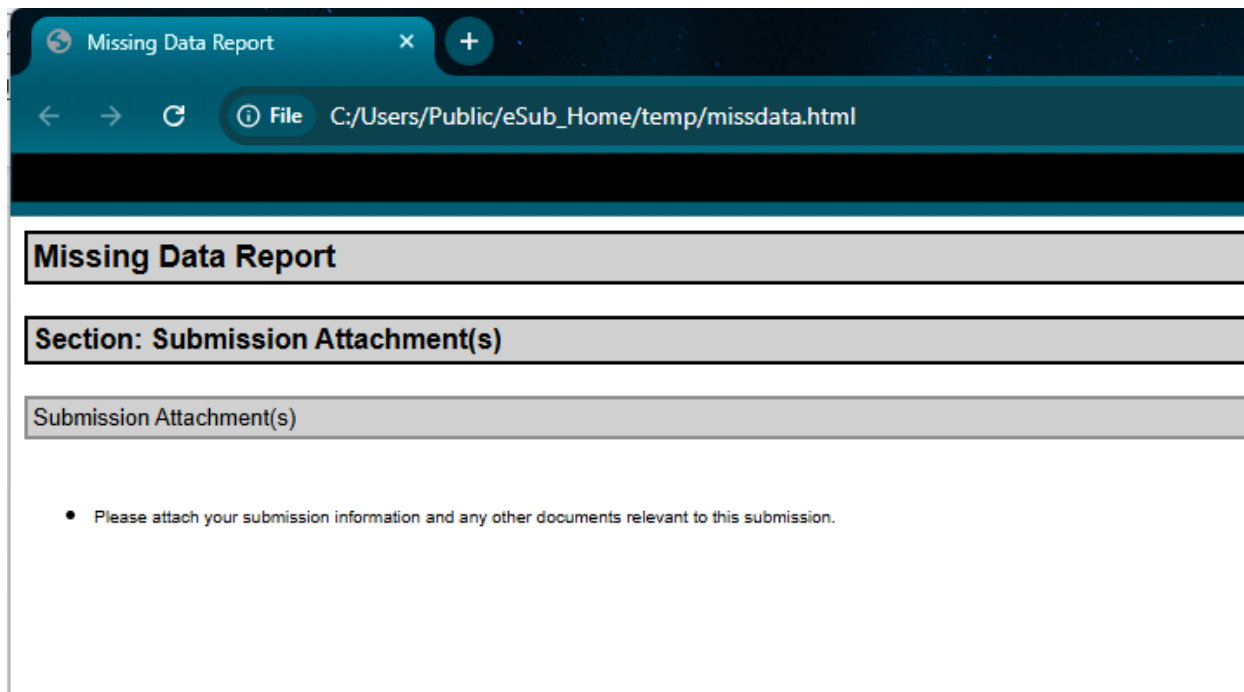
The next page is the end page for data entry. There is no content to enter on this screen. The user will need to select the package button to start packaging the submission. Instructions are available in the box on the screen.



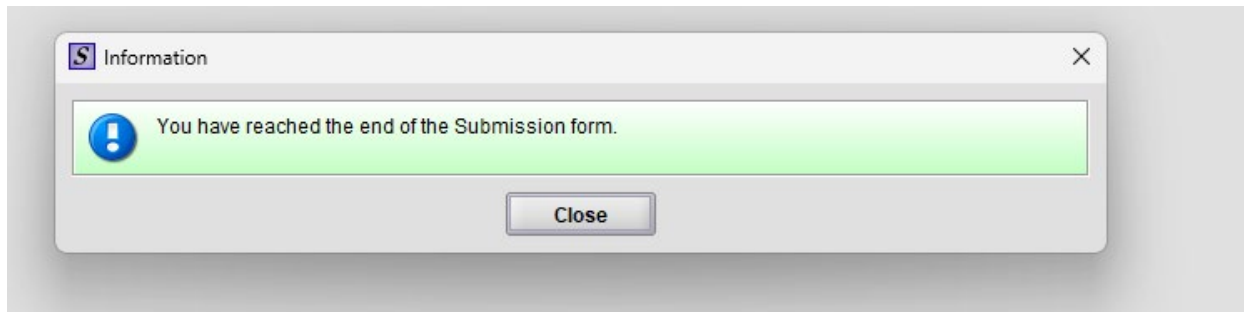
If a mandatory field is missing, a missing data report will be provided. Users can click the yes button to review the missing data report.



The missing data report will appear as follows:



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.

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Packaging Files Dialog

Packaging Submission Files

Step 1 Overview and Package File Information





What Submission Packaging Entails...

After completing the submission and verifying there is no information missing, you are ready to package the files for submission. It is important to note that the packaging process may differ based on the submission to be filed. "Click" the hint option (i.e., light bulb icon) for additional information on each step of the process.

During the packaging process, you will verify all file attachments, select your transmission approach (may not be available for certain submission types), and produce a complete submission file. The packaging process will result in a single ZIP file per submission. The ZIP file generated by eSubmitter should not be altered in any way prior to transmitting to FDA.

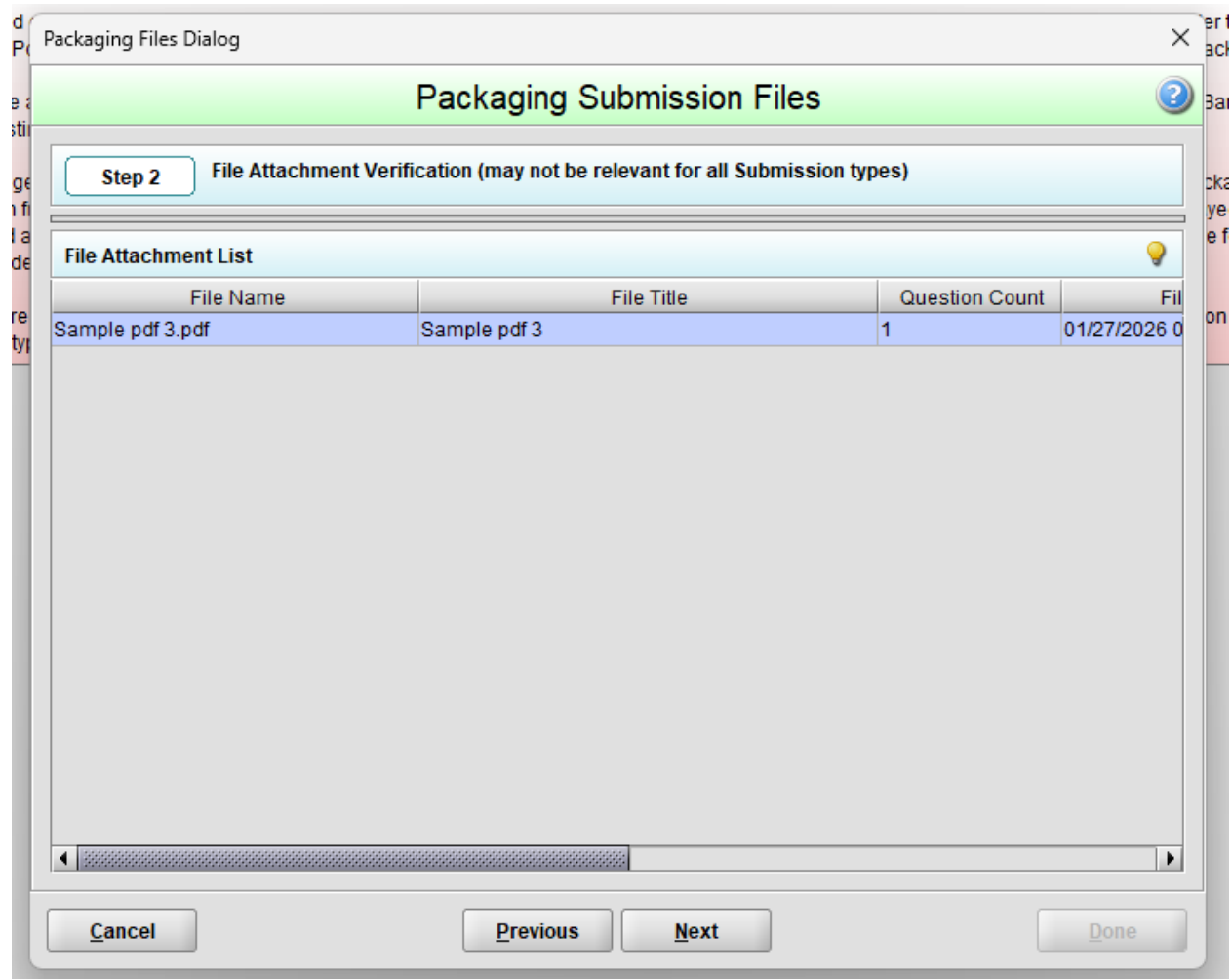
For detailed instructions on packaging your submission files, see the [eSubmitter User Manual](#) or the eSubmitter Help (located on the Menu bar within the eSubmitter application).

General Submission Package Information

- Package File Name  Sample_WP
- Package Output Location  [redacted] \output\  

Cancel **Previous** **Next** **Done**

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.



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.

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 ☒
- 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](#) 0%

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

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 ☒ [Redacted] CTPeSubmissionsHelpDesk.pfx   
- Digital Signature ☒ [Redacted]

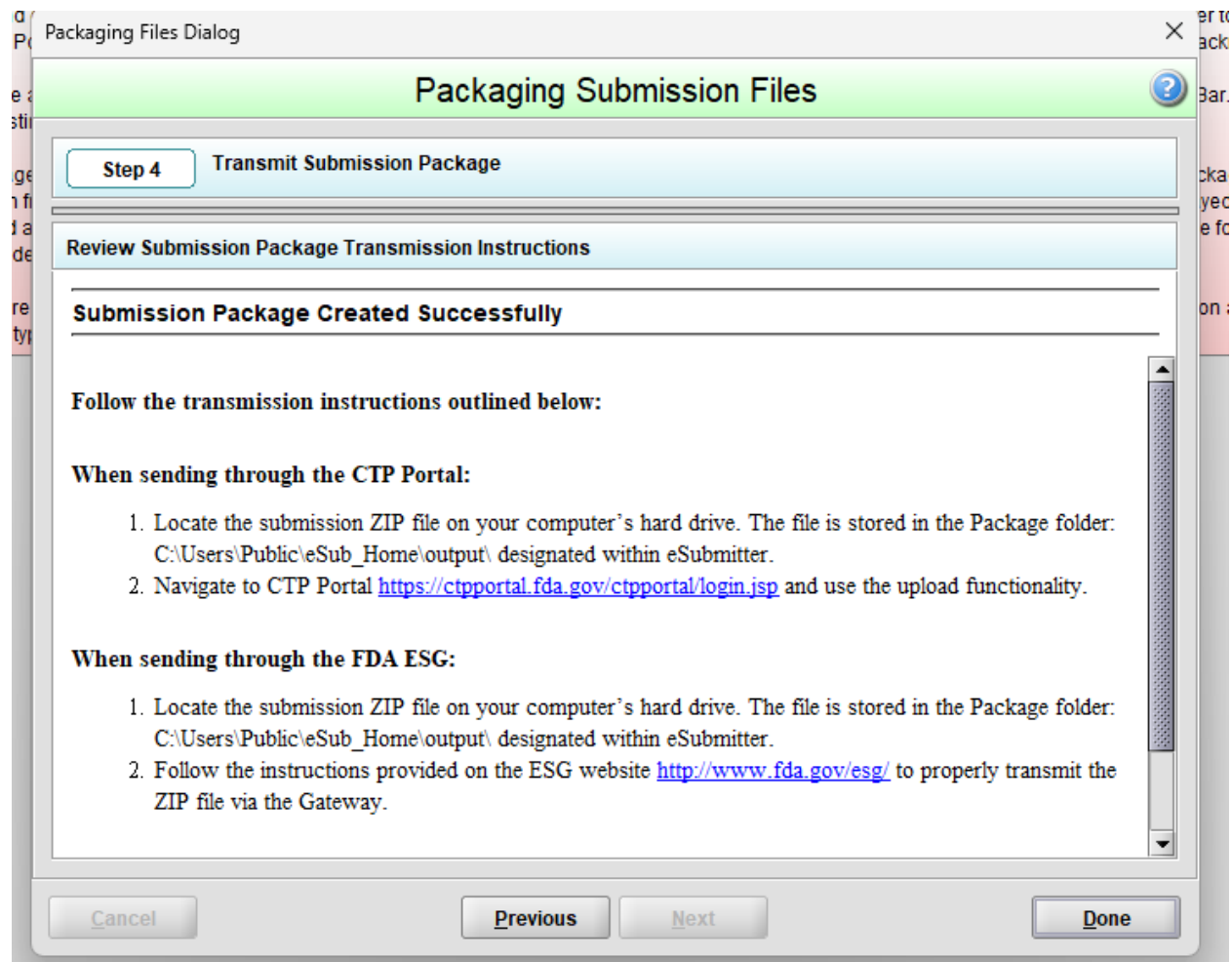
Produce Submission Package

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

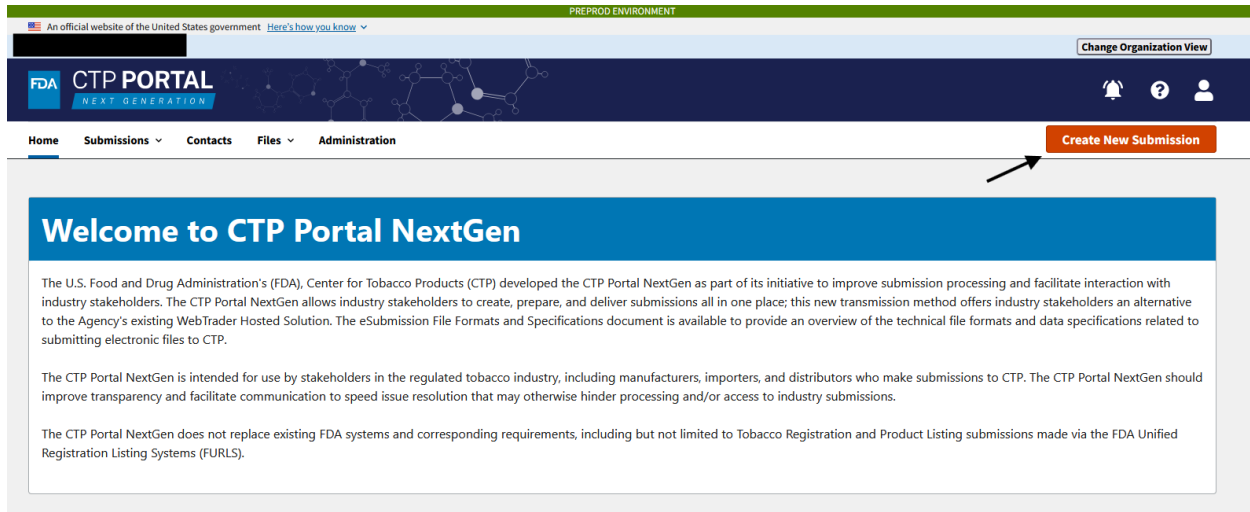
[Package & Sign Submission Files](#) Complete.

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

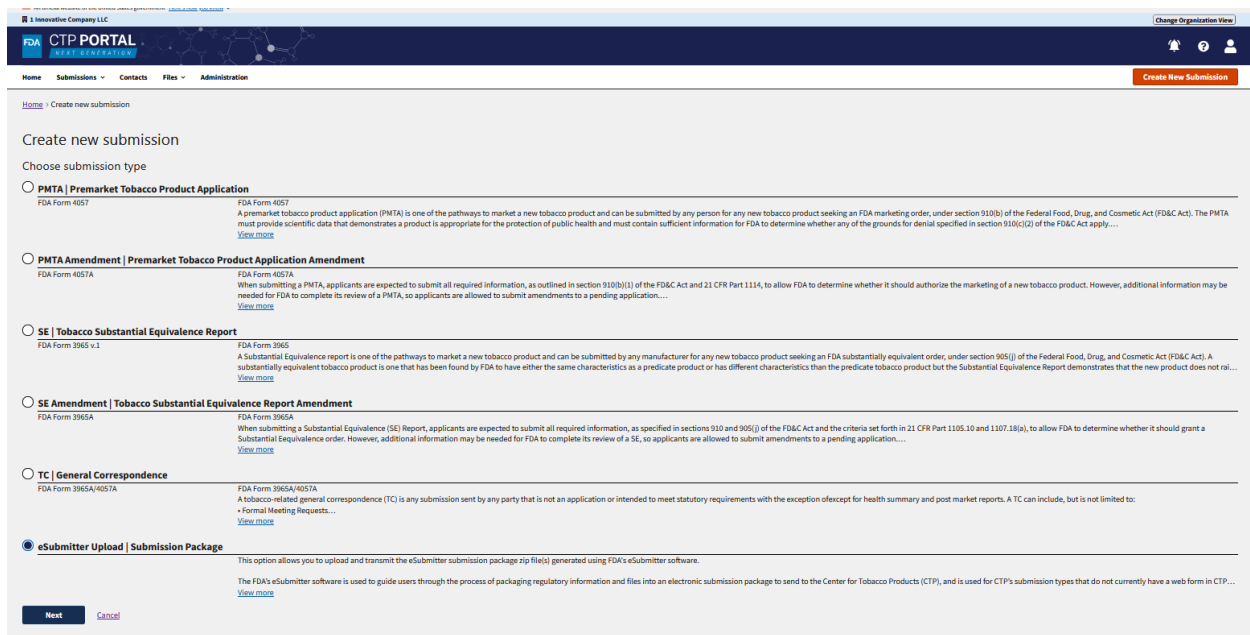
The next page contains information on how to submit. There is no content to enter on this screen. The user can press next to move to the next page.



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



User will select eSubmitter Upload.



The user will browse to and select the eSubmitter file.

The screenshot shows the 'Upload File' page in the FDA CTP Portal. The header includes the FDA logo, 'CTP PORTAL', and 'NEXT GENERATION'. Navigation links are 'Home', 'Submissions', 'Contacts', 'Files', and 'Administration'. A 'Create New Submission' button is in the top right. The breadcrumb trail is 'Home > Create new submission > eSubmitter Upload'. The main heading is 'Upload File'. Below it, a message states: 'Use the browse button to locate the zip file you wish to upload. CTP NextGen only allows eSubmitter zip files to be uploaded and only one zip file can be loaded at a time. Download eSubmitter: www.fda.gov/industry/fda-esubmitter.' The 'File Name' field contains 'Sample_WP.zip' and has a 'Browse' button. The 'Description' field contains 'This is a sample upload screen for **PDA** purposes'. A checkbox is checked with the text 'I hereby certify that the information provided herein is true and that I am authorized to upload a submission with the FDA.' At the bottom are 'Upload' and 'Cancel' buttons. A small '48' is in the bottom right corner.

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 'eSubmitter Upload Success' page in the FDA CTP Portal. The header is identical to the previous screen. The breadcrumb trail is 'Home > Create new submission > eSubmitter Upload > eSubmitter Upload Success'. A large green checkmark icon is on the left. The main 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 two buttons: 'Upload New eSubmitter File' and 'View eSubmitter Uploads'.