

Electronic Submission of 806 Reports of Corrections and Removals

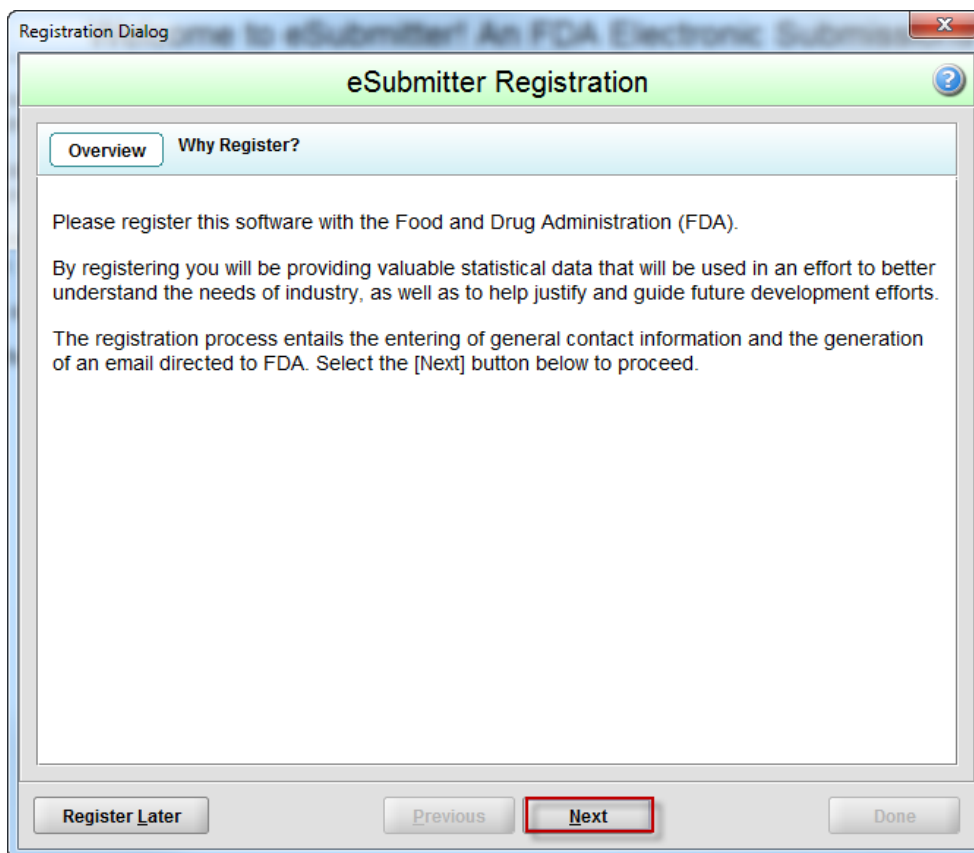
This tutorial provides instructions for completing Center for Devices and Radiological Health's (CDRH's) electronic submission of Medical Devices Corrections and Removals Reports.

Introduction to eSubmitter System

If you already have eSubmitter installed and registered (please make sure that you have provided contact information and address during registration), go to step 5a to start the process of creating the Corrections and Removals Report.

If you do not have eSubmitter installed on your desktop, click the hyperlink and follow applicable instructions. <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm> . Afterwards, review the information below and follow steps 1-4 to register.

Step 1: Open eSubmitter using the above link. A Registration Dialog pop-up box will appear. Review "Why Register?" then, click "Next". Proceed to step 2.



Step 2: Enter the Contact Information. Click “Next”, and proceed to step 3.
Remember: All blue dot information is required by Title 21 Code of Federal Regulations Part 806 (21 CFR 806).

Registration Dialog **eSubmitter Registration**

Step 1 Enter Contact Information

Contact

Title (e.g., Mr., Ms.):	
First/Given Name:	Sweet
Middle Name:	
Last Name:	Pea
Suffix (e.g., Sr, Jr, III):	
Degree(s) (e.g., PhD, JD):	
Occupation Title:	
Email Address:	sweet.pea@fda.hhs.gov

Buttons: Register Later, Previous, **Next**, Done

Step 3: Enter your address information. Click, “Next” and proceed to step 4a.

Step 2 Enter Address Information

Address

Establishment Name:	FDA
Country:	<input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below)
Address - Line 1:	10903 New Hampshire Avenue
Address - Line 2:	
City:	Silver Spring
State, Province, or Territory:	Maryland
Post Office or Zip Code:	20993-____

Phone Numbers

Telephone number:	(301) 796-0000 Ext. ____
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Buttons: Register Later, Previous, **Next**, Done

Step 4a: Verify the information is correct. Click the Generate Email link to send an email from eSubmitter to your inbox. Click "Next". Proceed to step 4b.

Step 3 Generate Email

You provided the following information:

Brenda Bell

brenda.bell@fda.hhs.gov

FDA
10903 New Hampshire Avenue
Silver Spring, MD, 20993, US
(301) 796-0000

Please verify the information and select the link below to generate an email to send to FDA.

[Generate Email](#)

Note: We will attempt to generate the email using your local email application. After the email is generated and your email software is loaded, send it as you would any other email.

Register Later Previous **Next** Done

Step 4b: Check your inbox.

If an email was sent from FDA eSubmitter, proceed to step 4c.

If you did not receive an email, proceed to step 4d.

MailTips could not be retrieved.

To... FDA eSubmitter

CC...

Bcc...

Send

Subject: eSubmitter Registration

// NOTE: DO NOT MODIFY THE CONTENT WITHIN THIS EMAIL //

TitleName=
FirstName=Brenda
MiddleName=
LastName=Bell
Occupation=|
Email=brenda.bell@fda.hhs.gov
Country=US
Establishment=FDA
Address1=10903 New Hampshire Avenue
Address2=
City=Silver Spring
StateProvinceTerritory=MD

Step 4c: If the registration email was sent successfully, choose “Yes, the Email was sent successfully.” Click “Done”, and proceed to step 5a.

Step 4 Check Results

Was the registration email sent successfully?

Yes the Email was sent successfully

No there was a Problem

If not, what was the issue?

No email was generated

All other issues

Registration completed. Select the [Done] option below to end the registration process.

Note: There will be no acknowledgement sent back by FDA in response to the email containing the registration information.

Register Later Previous Next **Done**

Step 4d: If the registration email was not sent successfully, choose “No there was a problem” and indicate the issue in the space provided. Click “Register Later.” Proceed to step 5a.

Step 4 Check Results

Was the registration email sent successfully?

Yes the Email was sent successfully

No there was a Problem

If not, what was the issue?

No email was generated

All other issues

Register Later Previous Next Done

Step 5a: Getting Started: When you are in the eSubmitter system, the following information will assist you with creating a complete report:



Blue dot indicates required 806 information.



Light bulb represents helpful hints.



Use "right" arrow to move forward to the next page.

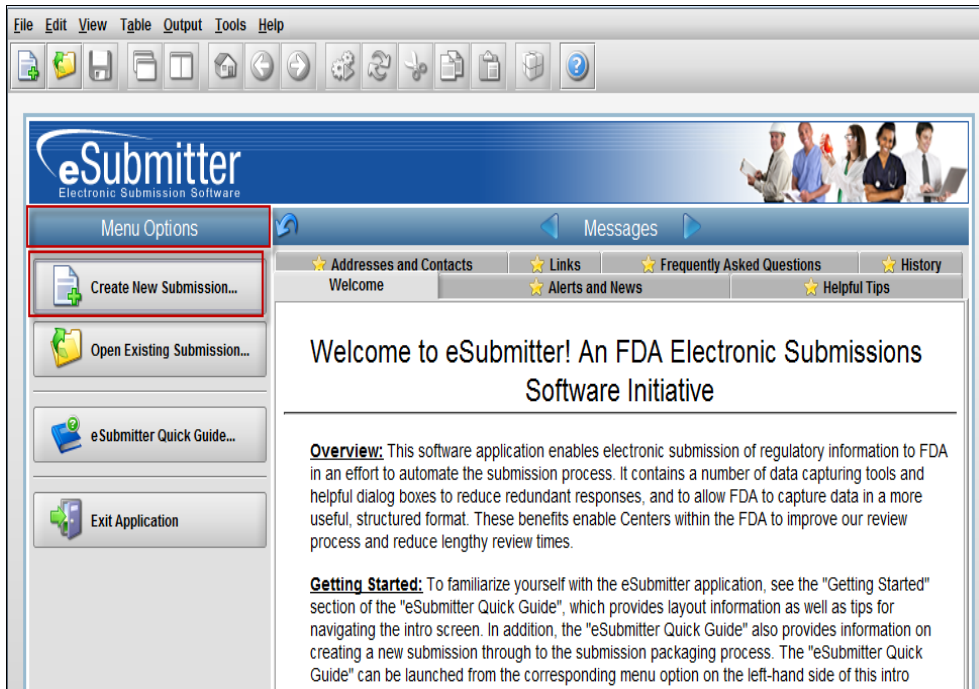


Use "left" arrow to move back to the previous page.

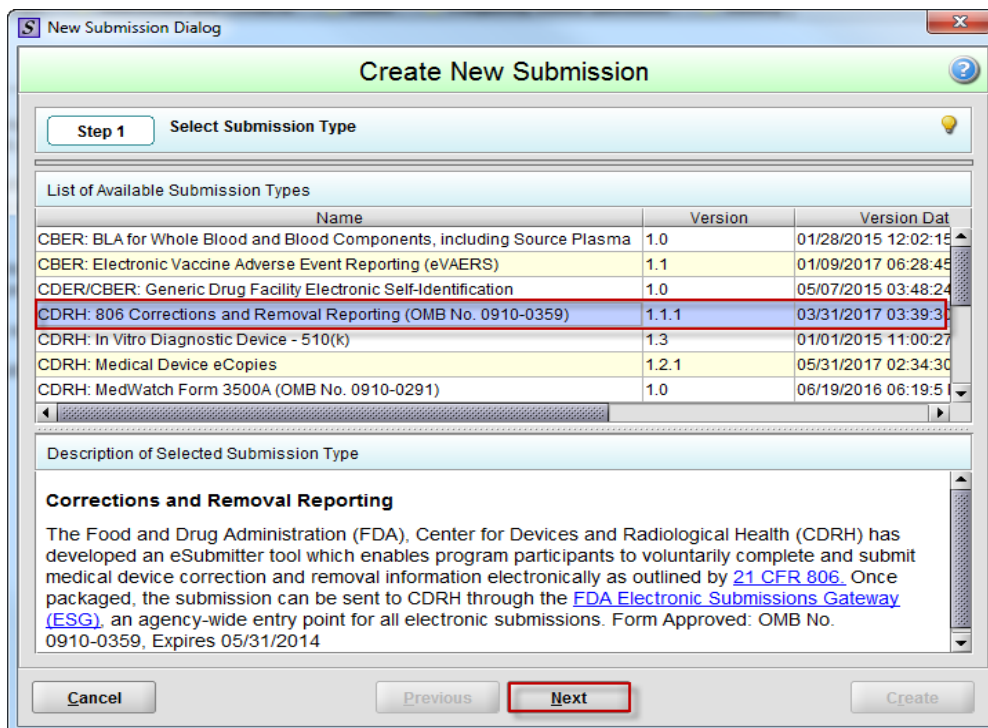
Note: All information requested by eSubmitter is necessary to complete the recall package (even if it is not per 21 CFR 806 reporting requirements). For example:

Submission Name: Recalls		Last Modified: 12/20/2016 12:57:25 PM	
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)		Date Packaged:	
Screen View		Corrections and Removals Report: Event Details	
Please select the regulatory violation being reported in this correction or removal:			
<input type="text"/>			
Firm Awareness Date		<input type="text" value="04/09/2016"/>	
Recall Initiation Date		<input type="text" value="04/11/2016"/>	
Method of Notification		<input type="text" value="Letter"/>	
▶ Method of Notification - Other		<input type="text"/>	

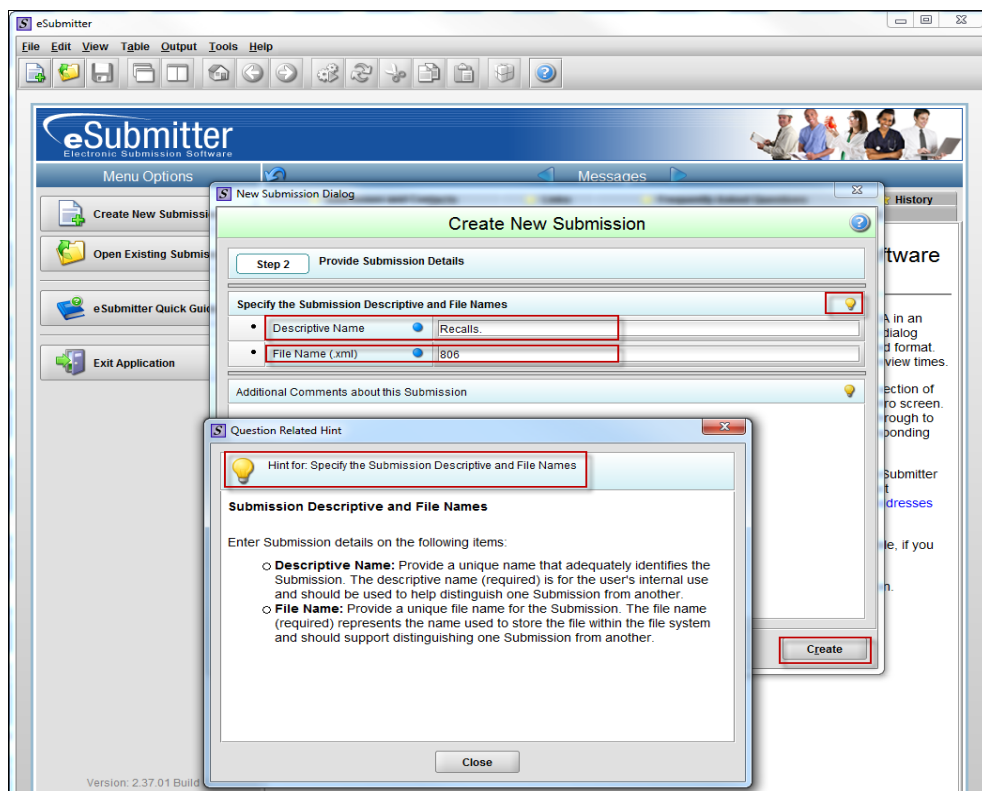
Step 5b: Creating a Medical Device Corrections and Removals Report--under “Menu Options”, click “Create New Submission.” Proceed to step 6.



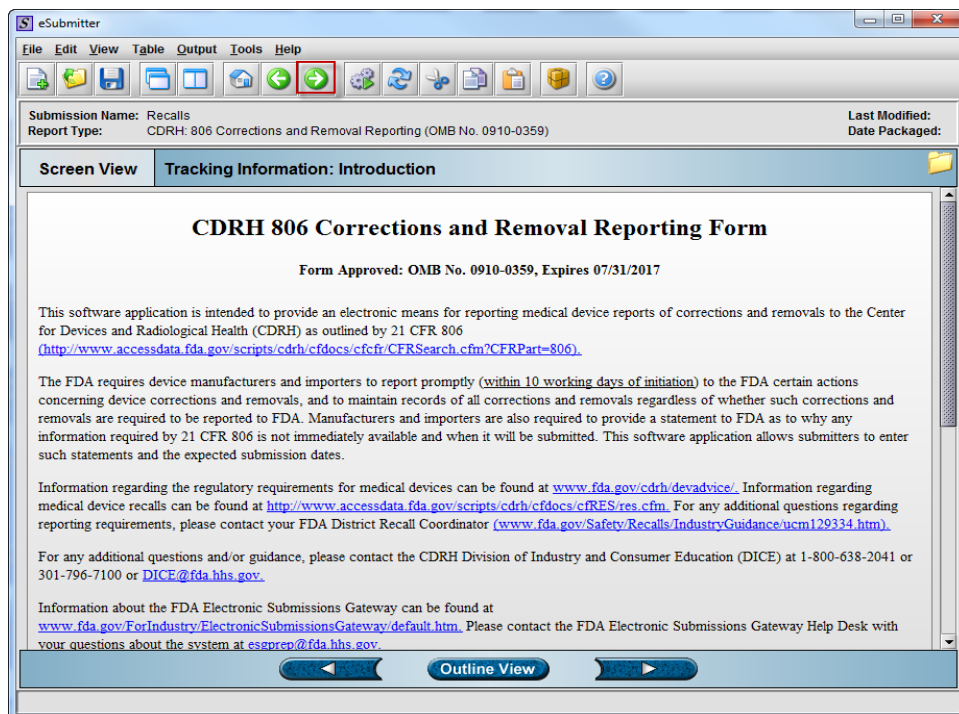
Step 6: When the New Submission Dialog pop up box appears, choose submission type: CDRH: 806 Corrections and Removals Reporting. Click “Next” and proceed to step 7.



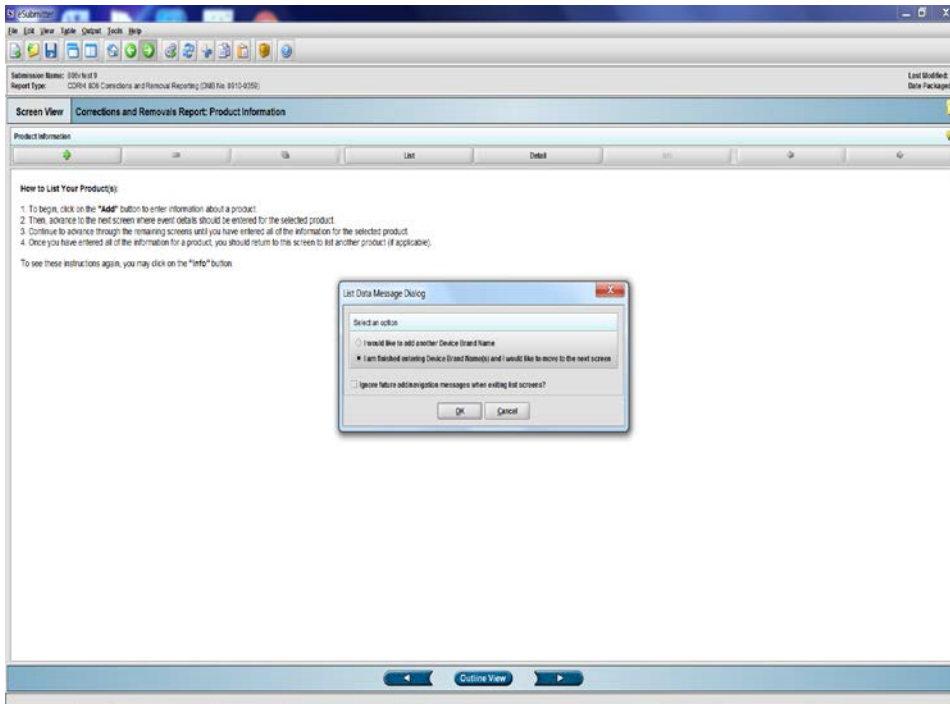
Step 7: Provide Submission Details. Enter Descriptive and File names. Provide any additional information about the submission as needed. Click “Create.” Option: If you need assistance, click the light bulb for help on how to enter the information. Proceed to step 8a.



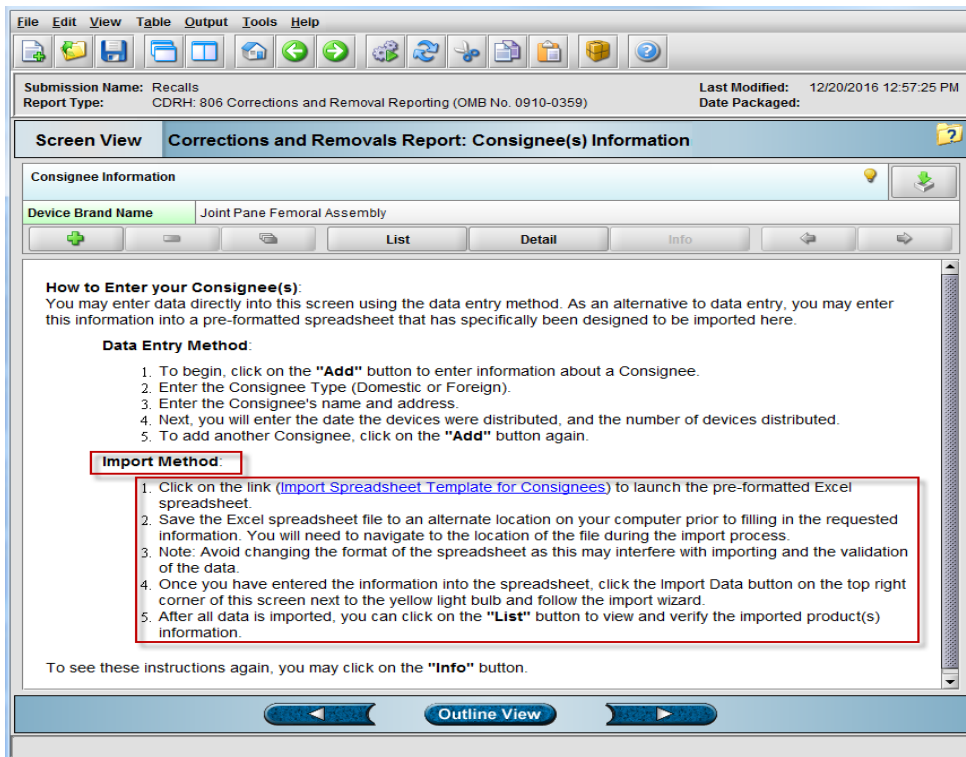
Step 8a: If this is your first time using eSubmitter for 806 reporting, read the CDRH 806 Corrections and Removals Reporting Form information. Click the “Next” arrow until you see the **Consignee Information** screen. Then proceed to Step 8b for instructions to download the Excel spreadsheet. If you have previously registered and downloaded the Excel spreadsheet, proceed to Step 9.




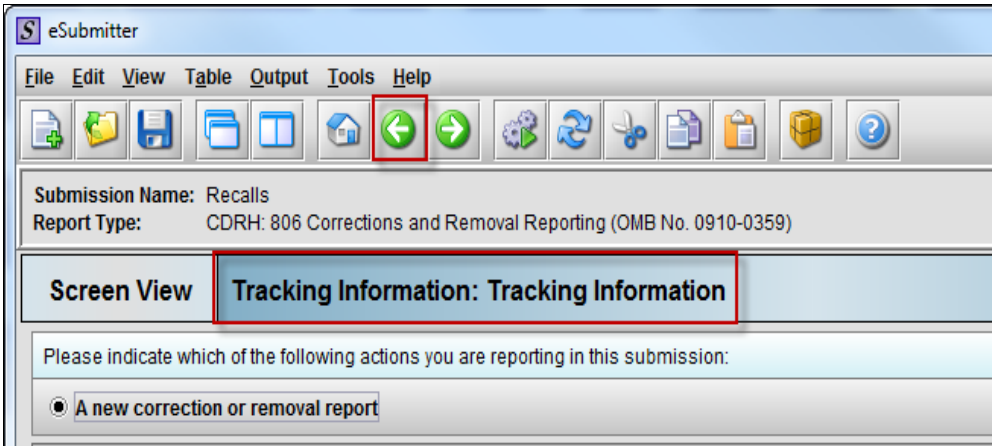
Click on "OK" button to proceed to the **Consignee Information** screen



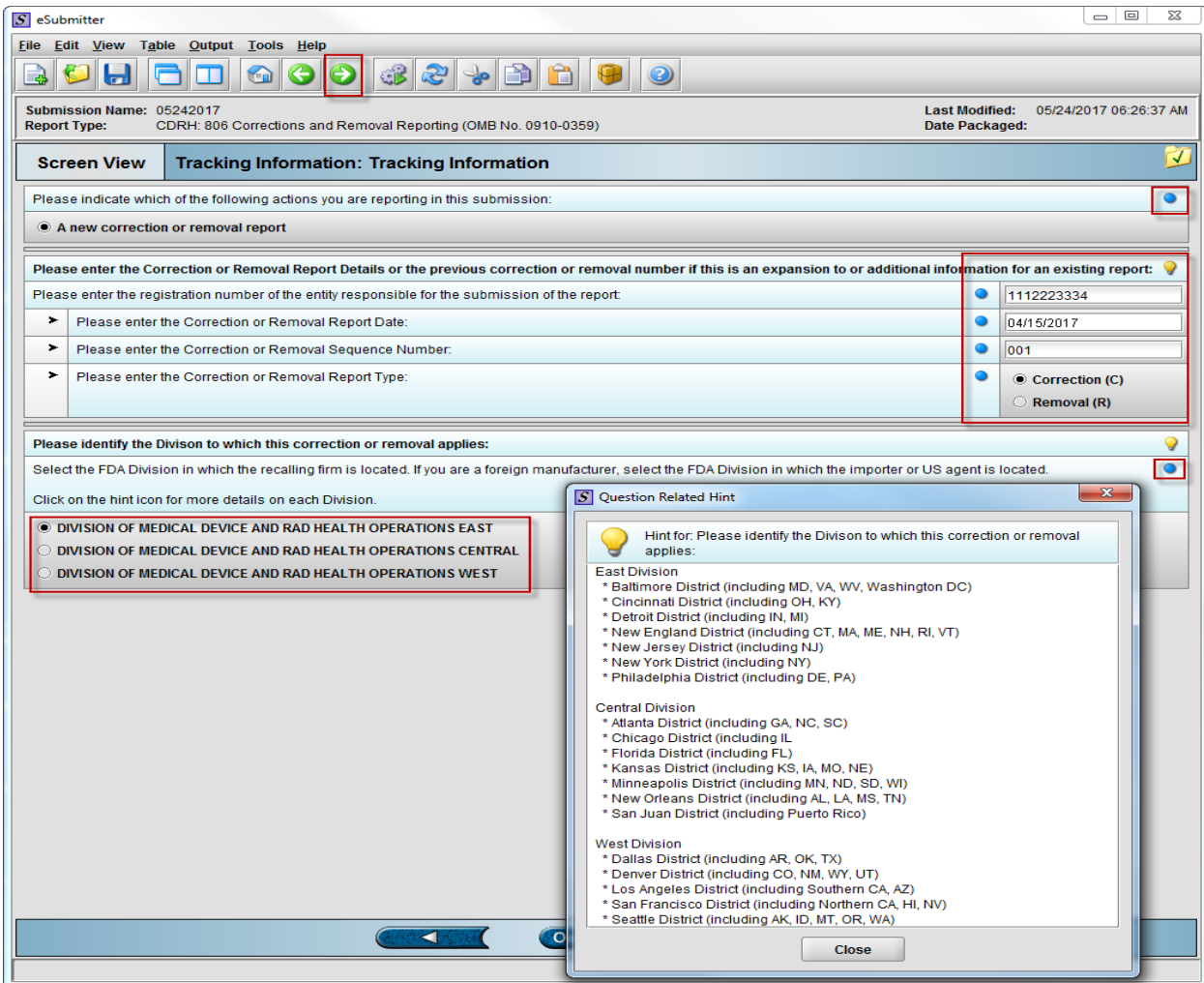
Step 8b: Review and follow the Import Method instructions on the Consignee Information screen. Remember to save the pre-formatted Excel spreadsheet to your desktop. Complete the required fields on the spreadsheet. Use this spreadsheet to enter your consignee information into eSubmitter. You can use this spreadsheet for future Corrections and Removals reports. Proceed to step 8c.



Step 8c: Click on the “Previous” arrow  to go to the Tracking Information screen. Proceed to step 9.



Step 9: Complete the Tracking Information. Select the FDA Division in which the recalling firm is located. If you are a foreign manufacturer, select the FDA Division in which the importer or US agent is located. Click the “Next” arrow and proceed to step 10.



Step 10: Complete the Submitter Information. Proceed to Step 11.

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Recalls Last Modified: 12/12/2016 08:47:41 PM
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359) Date Packaged:

Screen View **Contact Information: Submitter Information**

Responsible Representative
Please provide the submitter contact and address information below.

Contact Information

Title (e.g., Mr., Ms.):	
First/Given Name:	Brenda
Middle Name:	
Last Name:	Bell
Occupation Title:	CSO
Email Address:	brenda.bell@fda.hhs.gov


Address

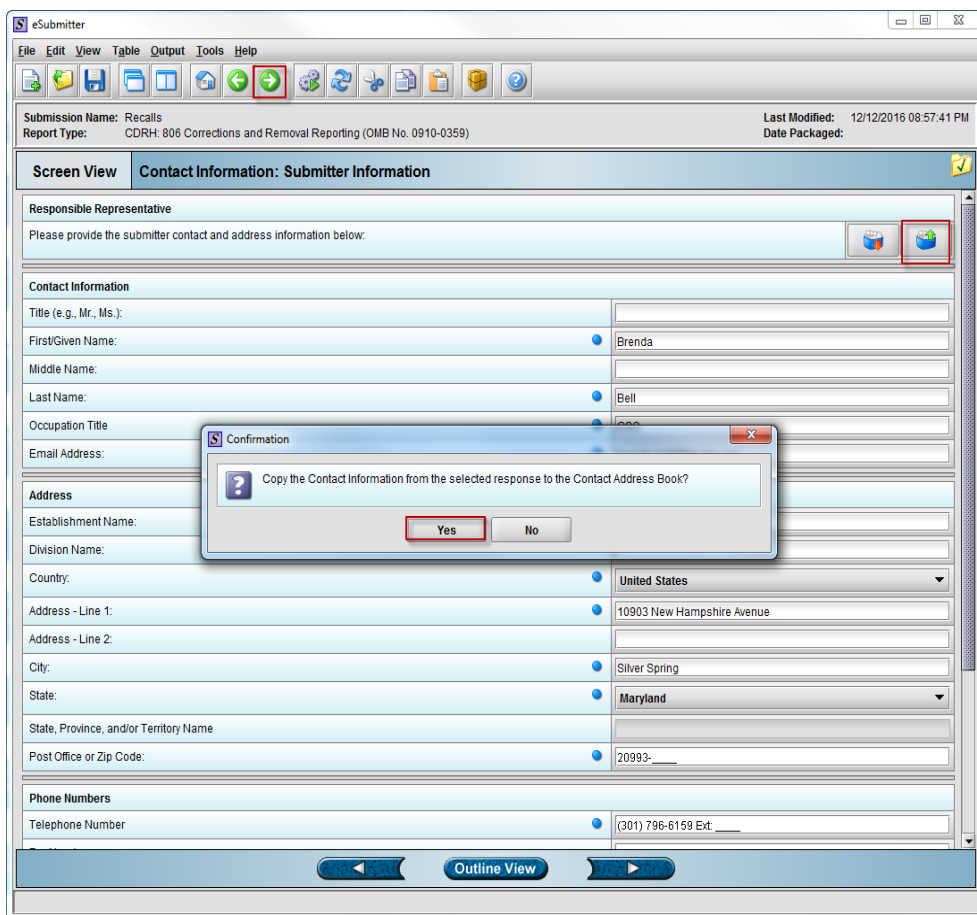
Establishment Name:	FDA
Division Name:	
Country:	United States
Address - Line 1:	10903 New Hampshire Avenue
Address - Line 2:	
City:	Silver Spring
State:	Maryland
State, Province, and/or Territory Name:	
Post Office or Zip Code:	20993-____

Phone Numbers

Telephone Number:	(301) 796-6159 Ext. ____
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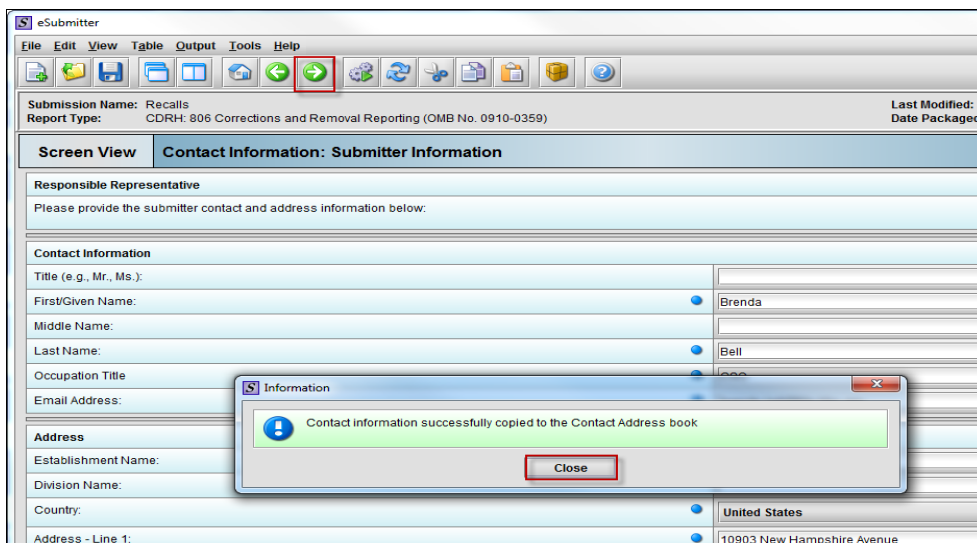
Outline View

Step 11: Click on the Copy to Address Book button  to open the confirmation pop up box. Click “Yes” to copy the contact information to the contact address book. Click the “Next” arrow and proceed to step 12.



The screenshot shows the eSubmitter application window. The main form is titled "Contact Information: Submitter Information" and contains several sections: "Responsible Representative", "Contact Information", "Address", and "Phone Numbers". The "Contact Information" section includes fields for Title, First/Given Name (Brenda), Middle Name, Last Name (Bell), Occupation Title, and Email Address. The "Address" section includes fields for Establishment Name, Division Name, Country (United States), Address - Line 1 (10903 New Hampshire Avenue), Address - Line 2, City (Silver Spring), State (Maryland), State, Province, and/or Territory Name, and Post Office or Zip Code (20993-). The "Phone Numbers" section includes a field for Telephone Number ((301) 796-6159 Ext. ____). A "Confirmation" dialog box is overlaid on the form, asking "Copy the Contact Information from the selected response to the Contact Address Book?". The "Yes" button is highlighted with a red box. The "Next" arrow button is also highlighted with a red box.


Step 12: When the Information pop up box appears, click “Close”. Click the “Next” arrow. Proceed to step 13a if the manufacturer information is different from previously saved information. Proceed to step 13b if the manufacturer information is the same as previously saved information.



The screenshot shows the eSubmitter application window. The main form is titled "Contact Information: Submitter Information" and contains several sections: "Responsible Representative", "Contact Information", "Address", and "Phone Numbers". The "Contact Information" section includes fields for Title, First/Given Name (Brenda), Middle Name, Last Name (Bell), Occupation Title, and Email Address. The "Address" section includes fields for Establishment Name, Division Name, Country (United States), Address - Line 1 (10903 New Hampshire Avenue), Address - Line 2, City (Silver Spring), State (Maryland), State, Province, and/or Territory Name, and Post Office or Zip Code (20993-). The "Phone Numbers" section includes a field for Telephone Number ((301) 796-6159 Ext. ____). An "Information" dialog box is overlaid on the form, displaying a green bar and the message "Contact information successfully copied to the Contact Address book". The "Close" button is highlighted with a red box. The "Next" arrow button is also highlighted with a red box.

Step 13a: Enter “Manufacturer Information” if different from previously saved information. Repeat step 11.


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 status bar at the top indicates 'Submission Name: Recalls' and 'Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)'. The 'Last Modified' date is '12/13/2016 04:01:5 PM' and the 'Date Packaged' is blank. The main window title is 'Screen View Contact Information: Manufacturer Information'. Below the title is a help icon and a text box: 'The Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures.' Underneath is the 'Responsible Representative' section with the instruction: 'Please enter the following information about the Manufacturer below or select the information from the Address Book.' The form is divided into three main sections: 'Contact Information', 'Address', and 'Phone Numbers'. The 'Contact Information' section includes fields for Title, First/Given Name (Sweet), Middle Name, Last Name (Pea), Occupation Title, and Email Address. The 'Address' section includes Establishment Name, Division Name, Country (United States), Address - Line 1 (10995 New Hampshire Avenue), Address - Line 2, City (Silver Spring), State (Maryland), State, Province, and/or Territory Name, and Post Office or Zip Code (20993). The 'Phone Numbers' section includes Telephone Number ((301) 796-6158 Ext: 111) and Fax Number. At the bottom of the form are 'Reference Numbers' and 'Outline View' buttons. A 'Confirmation' dialog box is overlaid on the form, asking 'Copy the Contact Information from the selected response to the Contact Address Book?' with 'Yes' and 'No' buttons.

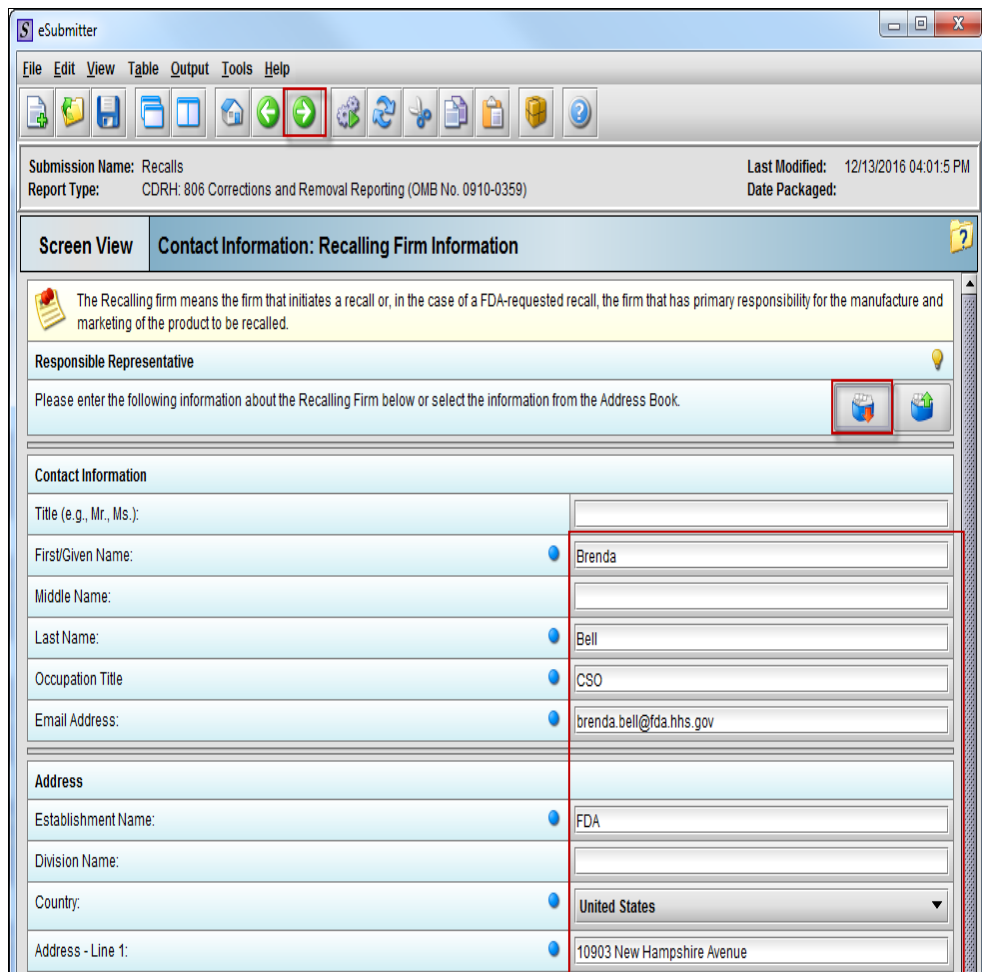
Step 13b: If information is the same as previously saved information, click on the Copy From button  to open the Select from Contact List pop up box. Click the appropriate contact and click “Select”. The contact information will fill the Contact Information fields. Click the “Next” arrow and proceed to step 14.

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 status bar at the top indicates 'Submission Name: Recalls' and 'Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)'. The 'Last Modified' date is '12/13/2016 04:01:5 PM' and the 'Date Packaged' is blank. The main window title is 'Screen View Contact Information: Manufacturer Information'. Below the title is a help icon and a text box: 'The Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures.' Underneath is the 'Responsible Representative' section with the instruction: 'Please enter the following information about the Manufacturer below or select the information from the Address Book.' The form is divided into three main sections: 'Contact Information', 'Address', and 'Phone Numbers'. The 'Contact Information' section includes fields for Title, First/Given Name, Middle Name, Last Name, Occupation Title, and Email Address. The 'Address' section includes Establishment Name, Division Name, Country, Address - Line 1, Address - Line 2, City, State, State, Province, and/or Territory Name, and Post Office or Zip Code. The 'Phone Numbers' section includes Telephone Number and Fax Number. At the bottom of the form are 'Reference Numbers' and 'Outline View' buttons. A 'Select from Contact List' dialog box is overlaid on the form. The dialog has a title bar 'Contact List Dialog' and a subtitle 'Select from Contact List'. It contains a table with the following data:

Select a contact	Contact Name	Occupation Title	
<input type="checkbox"/>	Bell, Brenda	CSO	FD
<input checked="" type="checkbox"/>	Pea, Sweet	CSO	AR

Below the table is a text box for 'View comments on the selected contact'. At the bottom of the dialog are buttons for 'New...', 'Edit...', 'Delete', 'Select', and 'Close'.

Step 14: Enter the “Recalling Firm Information” or select the information from the Address Book by clicking the Copy From button . If you click the Copy From button, select a contact from the list. Click the “Next” arrow and proceed to step 15.



eSubmitter

File Edit View Table Output Tools Help

Submission Name: Recalls Last Modified: 12/13/2016 04:01:5 PM
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359) Date Packaged:

Screen View Contact Information: Recalling Firm Information

The Recalling firm means the firm that initiates a recall or, in the case of a FDA-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

Responsible Representative

Please enter the following information about the Recalling Firm below or select the information from the Address Book.


Contact Information

Title (e.g., Mr., Ms.):	
First/Given Name:	Brenda
Middle Name:	
Last Name:	Bell
Occupation Title	CSO
Email Address:	brenda.bell@fda.hhs.gov

Address

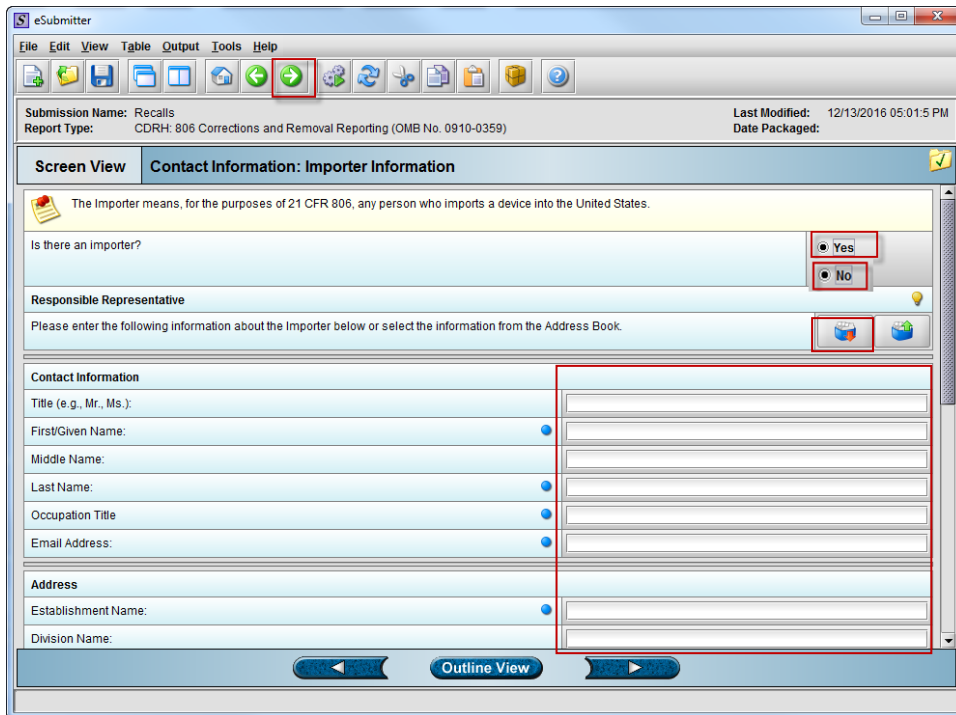
Establishment Name:	FDA
Division Name:	
Country:	United States
Address - Line 1:	10903 New Hampshire Avenue

Step 15: On the “Importer Information” page:

Select “Yes” if there is an importer. Either enter the contact information, or click the Copy From button  to select information from the Address Book.

Select “No” if there is no importer.


Click the “Next” arrow and proceed to step 16.



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, with the 'Next' arrow icon highlighted by a red box. The main content area is titled 'Contact Information: Importer Information' and includes a definition of an importer, a question 'Is there an importer?' with 'Yes' and 'No' radio buttons (the 'Yes' button is selected and highlighted with a red box), and a 'Responsible Representative' section with a 'Copy From' button (also highlighted with a red box). Below this are input fields for 'Contact Information' (Title, First/Given Name, Middle Name, Last Name, Occupation Title, Email Address) and 'Address' (Establishment Name, Division Name). The 'Next' arrow in the bottom toolbar is also highlighted with a red box.

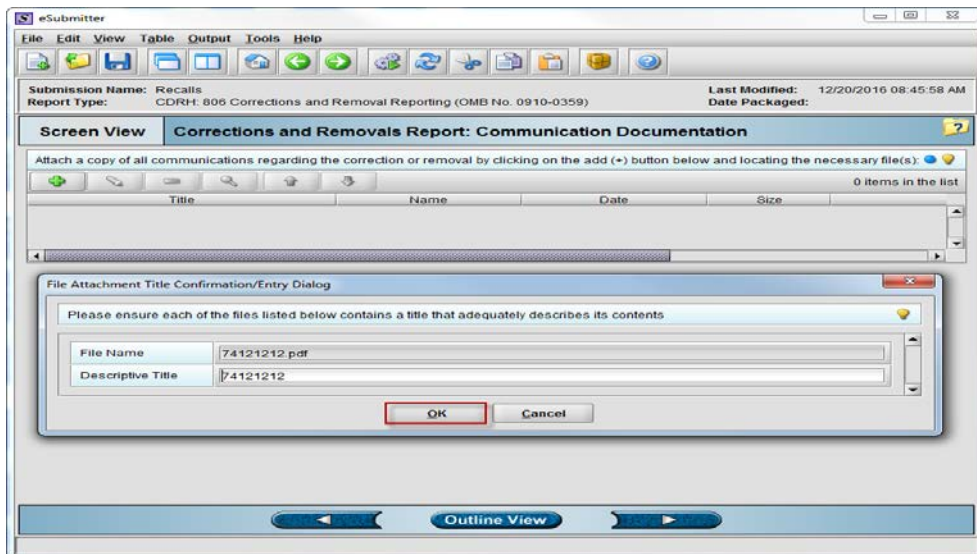
Step 16: Complete the “Event Details”. Click the Next arrow and proceed to step 17a.

The screenshot shows the 'eSubmitter' application window with the 'Corrections and Removals Report: Event Details' screen. The 'Next' arrow in the top toolbar is highlighted with a red box. The form contains several fields: 'Firm Awareness Date' (04/09/2016), 'Recall Initiation Date' (04/11/2016), and 'Method of Notification' (Letter). A red box highlights the date and notification method fields. Below these are three text areas for describing the event, corrective actions, and illnesses/injuries. The 'Outline View' button is visible at the bottom.

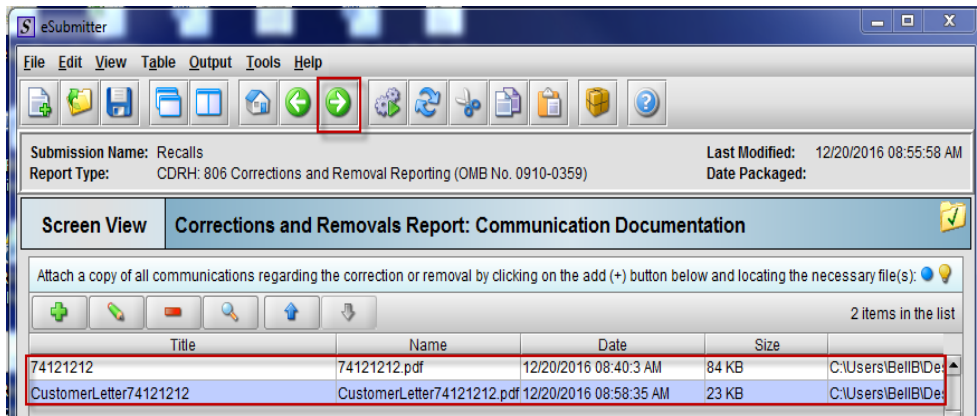
Step 17a: Attach a copy of all communication documents by clicking on the add button . When the pop up box appears, select the file from your computer. Click “Select” and proceed to step 17b.


The screenshot shows the 'eSubmitter' application window with the 'Corrections and Removals Report: Communication Documentation' screen. The 'Add' button (a green plus sign) is highlighted with a red box. A 'Select File to Attach' dialog box is open, showing a list of files in the 'Look In' folder '1214'. The file '74121212.pdf' is selected and highlighted with a red box. The 'File Name' field shows '74121212.pdf' and the 'Files of Type' is set to 'All Supported File Types'. The 'Select' button is also highlighted with a red box.

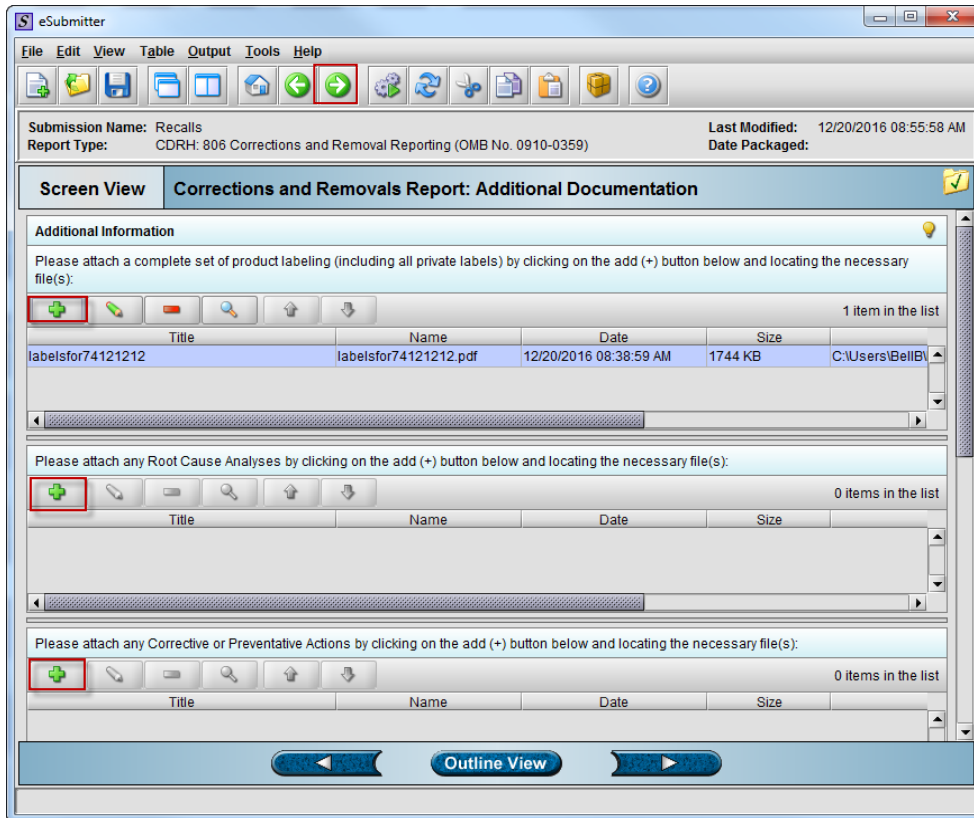
Step 17b: When the File Attachment Title Confirmation/Entry Dialog pop up box appears, click “OK.” Repeat the process until all desired documents are added. Proceed to step 17c.




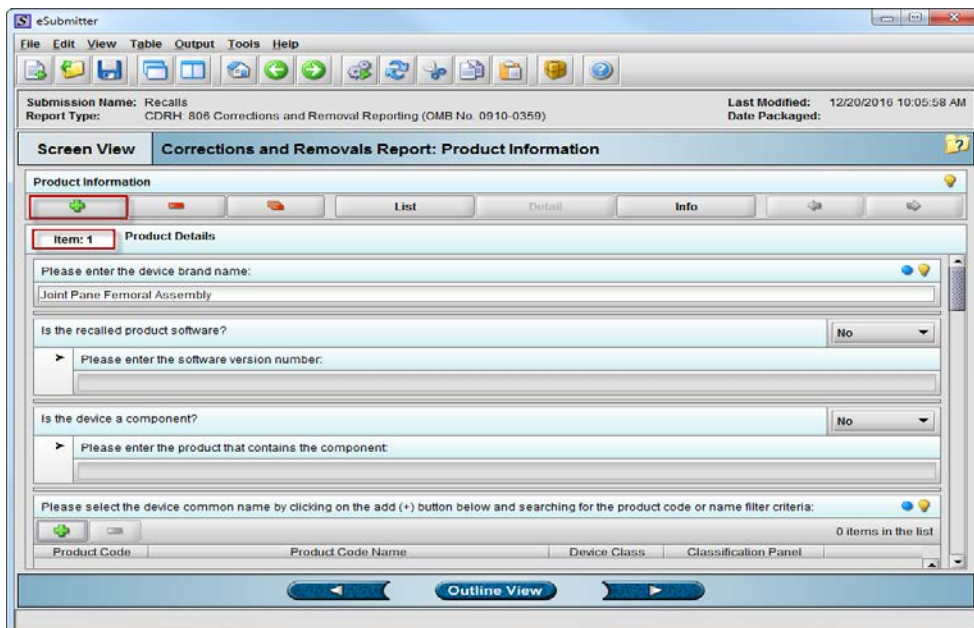
Step 17c: When all of your attached documents are listed, click the “Next” arrow. Proceed to step 18.



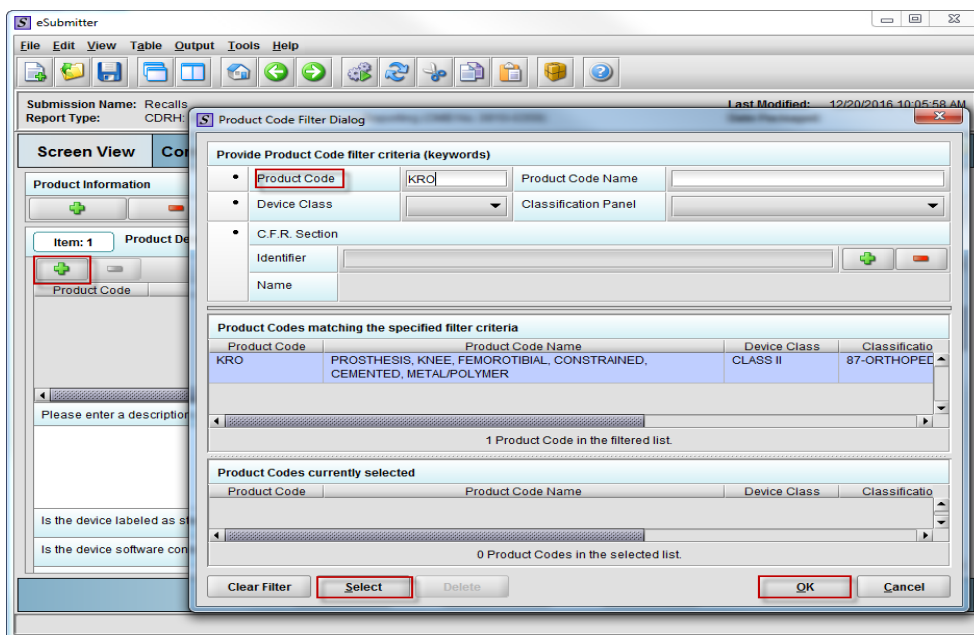
Step 18: Attach a complete set of product labeling and any other additional documentation by clicking on the add button . Follow steps 17a and 17b for locating and attaching the files. Click the “Next” arrow and proceed to step 19a.



Step 19a: Provide the product information by clicking the add button . Each product will be identified by Item # (i.e. Item:1, 2, etc.). Enter the requested information by answering all of the questions for each item. Proceed to step 19b.



Step 19b: Enter the product code. A Product Code Filter Dialog pop up box will appear. Product code fields will populate. Click "Select" then "OK". Proceed to step 19c.



Step 19c: Continue to enter the product information. Proceed to step 19d.

eSubmitter

Submission Name: Recalls
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)

Last Modified: 12/20/2016 11:35:58 AM
Date Packaged:

Screen View Corrections and Removals Report: Product Information

Product Information

Item: 1 Product Details

Please enter a description of the product:
System designed for use in patients with rheumatoid arthritis and primary and revision surgery

Is the device labeled as sterile? Yes

Is the device software controlled? No

Is the device tracked? No

Is the device an implant device? Yes

Please enter the device intended use:
Indicated for rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients.

Please enter the Unique Device Identifier (UDI), if known:

Outline View

Step 19d: Add the marketing status of the device. Provide the application number, if applicable, by clicking on the button. Proceed to step 19e.

eSubmitter

Submission Name: Recalls
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)

Last Modified: 12/20/2016 11:55:58 AM
Date Packaged:

Screen View Corrections and Removals Report: Product Information

Product Information

Item: 1 Product Details

Please enter the Unique Device Identifier (UDI), if known:

Please select the appropriate marketing status of the device:

- 510(k) Premarket Notification
- Premarket Approval (PMA)
- Exempt

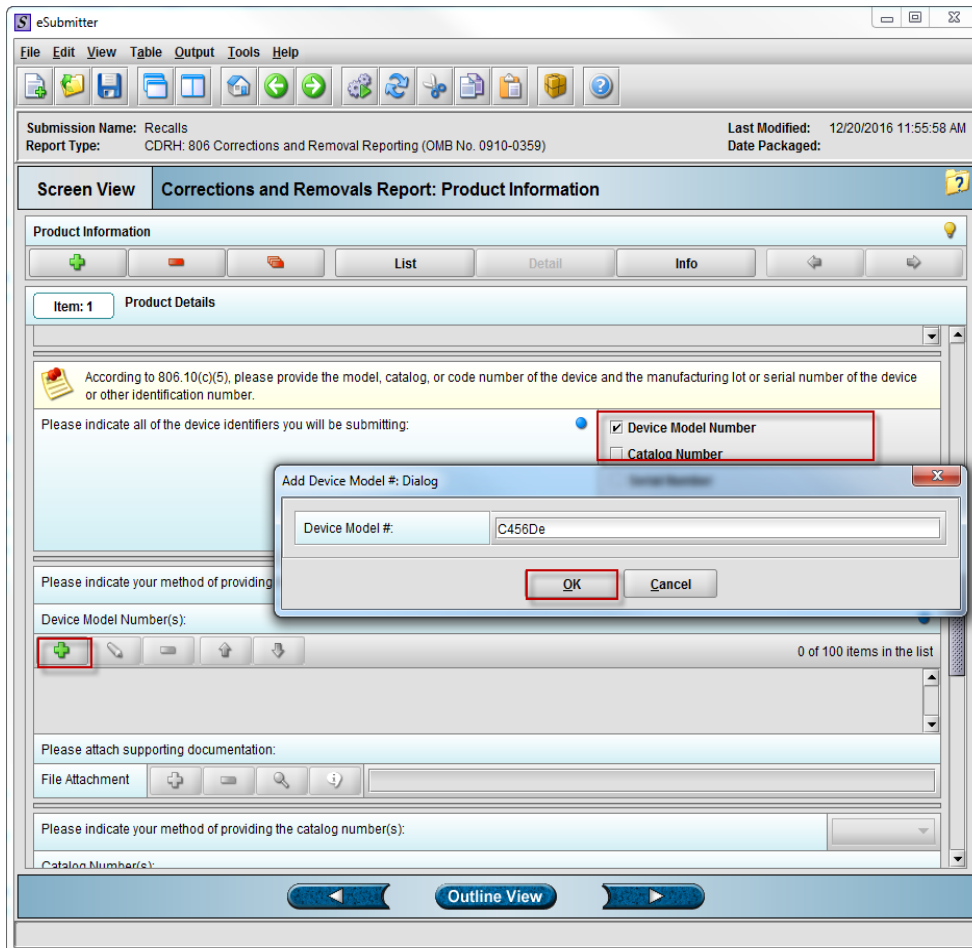
Please provide the 510(k) number:

Add Enter Number: Dialog

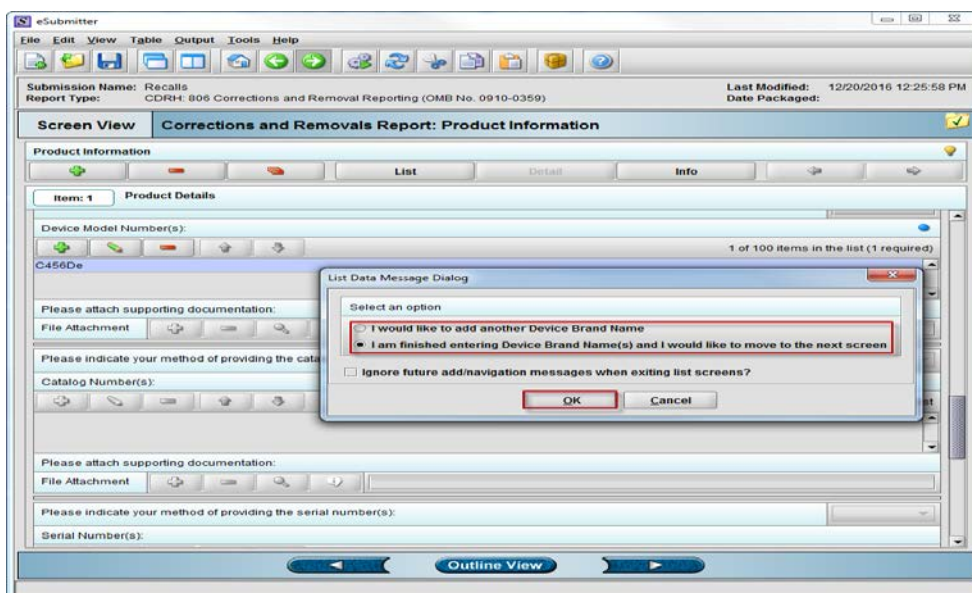
Enter Number: K000000012

OK Cancel

Step 19e: Add the device model number, catalog number, serial number, etc., if applicable. Proceed to step 19f.



Step 19f: When you have completed entering the product information, click Next, a List Data Message Dialog pop up box will appear. Select an option to move to the next screen or add another device brand name. If you chose to add another device brand name, repeat steps 19a-19e. Otherwise, proceed to step 20.



Step 20: Enter the requested correction or removal product details. There is a drop down box to enter Text Format or Date Format. Click "Next". Proceed to step 21.

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, with a green right-pointing arrow icon highlighted by a red box. Below the toolbar, the submission details are displayed: "Submission Name: Recalls", "Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)", "Last Modified: 12/20/2016 12:25:58 PM", and "Date Packaged:". The main area is titled "Screen View" and "Corrections and Removals Report: Correction or Removal Product Details". A "Device Brand Name" field contains "Joint Pane Femoral Assembly". The data entry section consists of several rows, each with a light blue header and a white input field. The first row has a header "Please enter the total number of devices manufactured subject to the correction or removal:" and a value of "5789". The second row has a header "Please enter the date range of manufacture:" and a date range from "01/20/2016" to "01/22/2016". The third row has a header "Please enter the total number of devices distributed subject to the correction or removal:" and a value of "700". The fourth row has a header "Please enter the date range of distribution:" and a date range from "03/22/2016" to "03/22/2016". The fifth row has a header "Please enter the total number in the same batch, lot or equivalent unit of production:" and a value of "500". The sixth row has a header "Please select the device expiration or expected end of life date format:" and a dropdown menu set to "Text Format". The seventh row has a header "Please enter the device expiration date or expected end of life date:" and a date field. The eighth row has a header "Please describe the device expiration date or expected end of life date:" and a text area containing "shelf life of 7 years". A red box highlights the date range fields and the dropdown menu.

Field Label	Value
Please enter the total number of devices manufactured subject to the correction or removal:	5789
Please enter the date range of manufacture:	01/20/2016 to 01/22/2016
Please enter the total number of devices distributed subject to the correction or removal:	700
Please enter the date range of distribution:	03/22/2016 to 03/22/2016
Please enter the total number in the same batch, lot or equivalent unit of production:	500
Please select the device expiration or expected end of life date format:	Text Format
Please enter the device expiration date or expected end of life date:	
Please describe the device expiration date or expected end of life date:	shelf life of 7 years

Step 21: Follow instructions under Import Method to import your completed Excel spreadsheet into the Consignee Information Section. Proceed to step 22a.

The screenshot shows the eSubmitter application window. At the top, there is a menu bar with 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. Below the menu bar is a toolbar with various icons. The main content area is titled 'Screen View Corrections and Removals Report: Consignee(s) Information'. It includes a 'Consignee Information' section with a 'Device Brand Name' field containing 'Joint Pane Femoral Assembly'. Below this are buttons for 'List', 'Detail', and 'Info'. A red box highlights a yellow lightbulb icon and a green download icon in the top right corner of the main content area. Below this, there are two sections: 'How to Enter your Consignee(s)' and 'Import Method'. The 'Import Method' section is highlighted with a red box and contains five numbered steps. At the bottom of the window, there is a blue bar with 'Outline View' and navigation arrows.

Submission Name: Recalls
Report Type: CDRH. 806 Corrections and Removal Reporting (OMB No. 0910-0359)
Last Modified: 12/20/2016 12:57:25 PM
Date Packaged:

Screen View Corrections and Removals Report: Consignee(s) Information

Consignee Information

Device Brand Name Joint Pane Femoral Assembly

List Detail Info

How to Enter your Consignee(s)
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 has specifically been designed to be imported here.

Data Entry Method:

1. To begin, click on the "Add" button to enter information about a Consignee.
2. Enter the Consignee Type (Domestic or Foreign).
3. Enter the Consignee's name and address.
4. Next, you will enter the date the devices were distributed, and the number of devices distributed.
5. To add another Consignee, click on the "Add" button again.

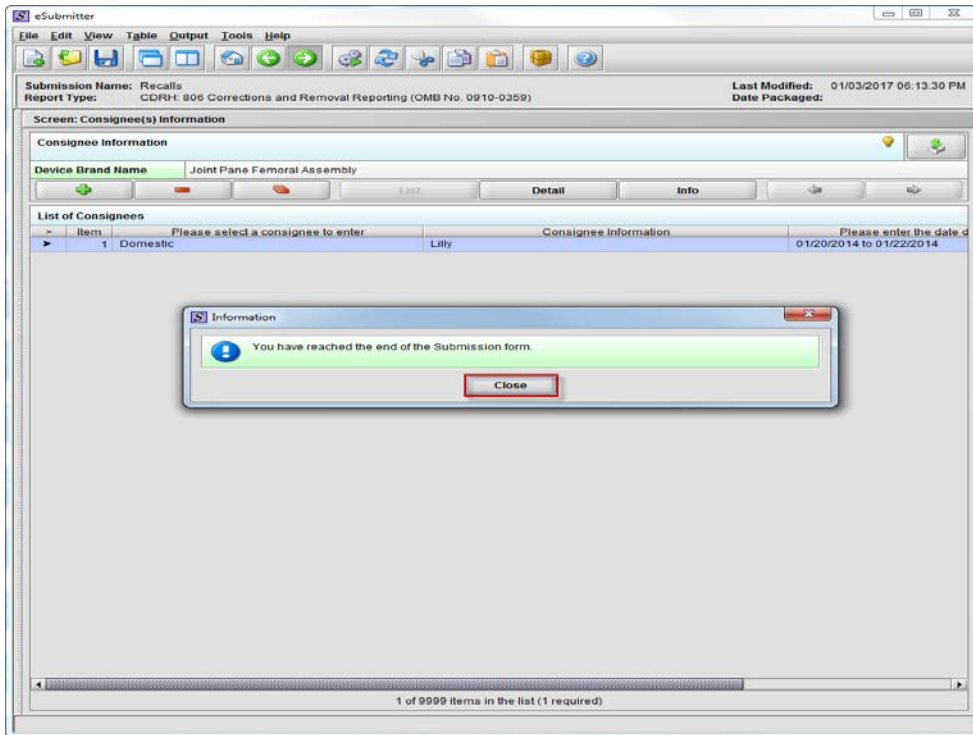
Import Method:

1. Click on the link ([Import Spreadsheet Template for Consignees](#)) to launch the pre-formatted Excel spreadsheet.
2. 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.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
4. 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.
5. After all data is imported, you can click on the "List" button to view and verify the imported product(s) information.

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



Outline View

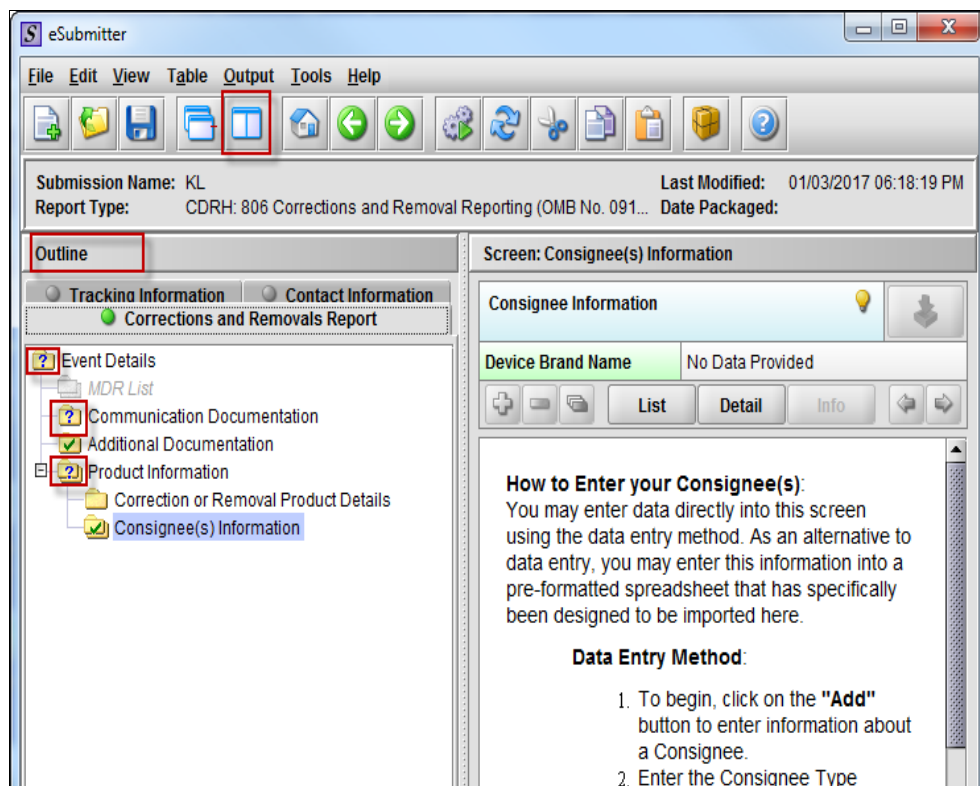
Step 22a: If an “Information” pop up box stating “You have reached the end of the submission form” appears, your report is complete. Close the information pop up box. Proceed to step 23a. If a “Warning” pop up box appears, proceed to step 22b.






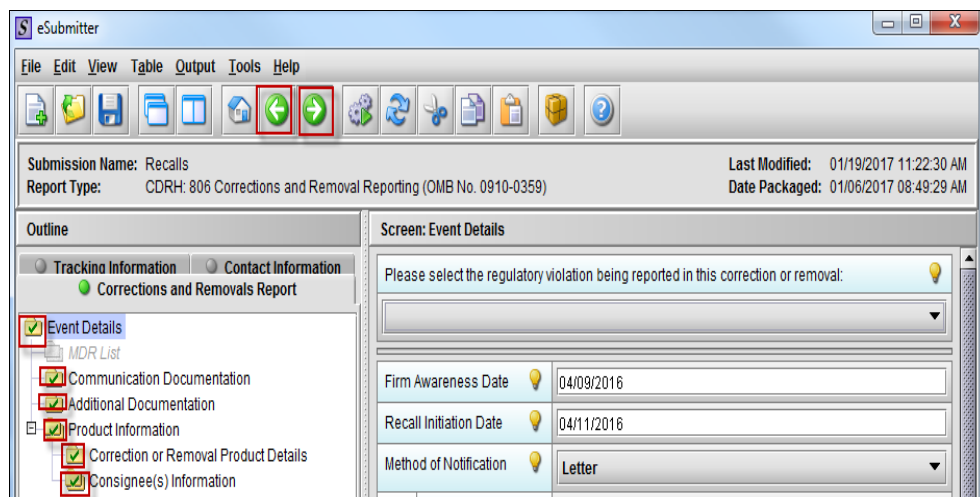
Step 22b: If a “Warning” pop up box stating “**You have reach the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses,**” click “Close” and proceed to step 22c.

The screenshot displays the eSubmitter application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The "Output" menu is highlighted with a red box. Below the menu bar, the submission details are shown: "Submission Name: Recalls", "Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)", "Last Modified: 12/20/2016 12:57:25 PM", and "Date Packaged:". The main content area is titled "Screen View Corrections and Removals Report: Consignee(s) Information". It features a "Consignee Information" section with a "Device Brand Name" field containing "Joint Pane Femoral Assembly". Below this are buttons for "List", "Detail", and "Info". A large text area provides instructions on how to enter consignee information, including a "Data Entry Method" section with a numbered list of steps. A "Warning" dialog box is overlaid on the screen, containing a yellow warning icon and the text: "You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses." The "Close" button in the dialog box is highlighted with a red box. At the bottom of the window, there are navigation buttons for "Outline View".

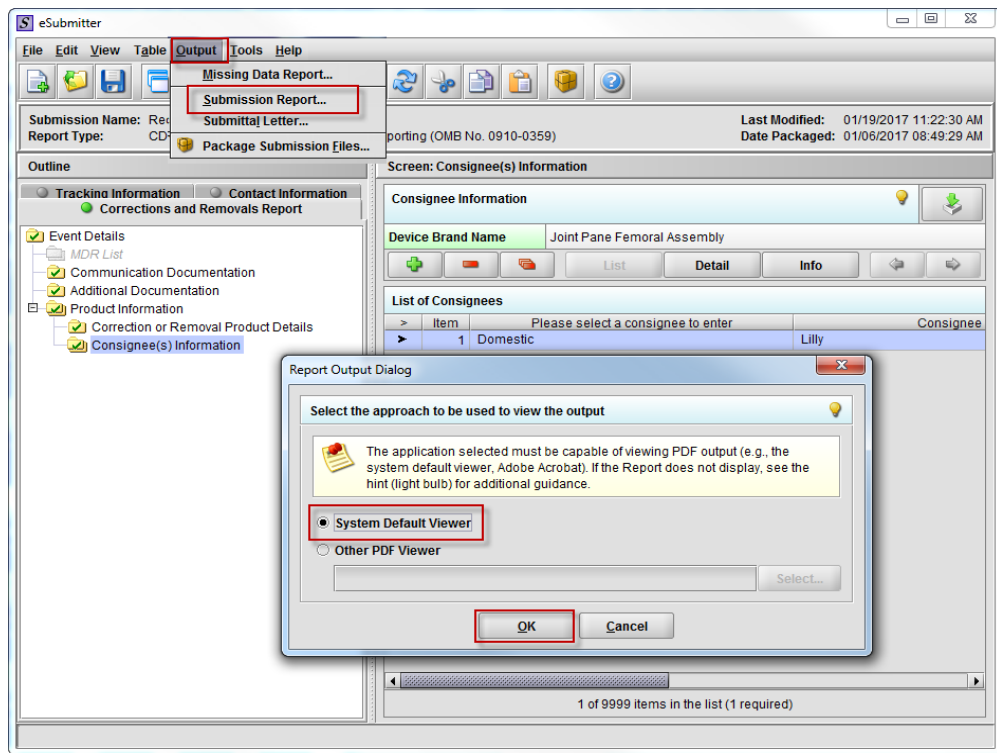
Step 22c: From the Menu Bar, click on the “Output” button . An outline of the sections where data is missing appears to the left of the screen and is represented by a question mark . Proceed to step 22d.




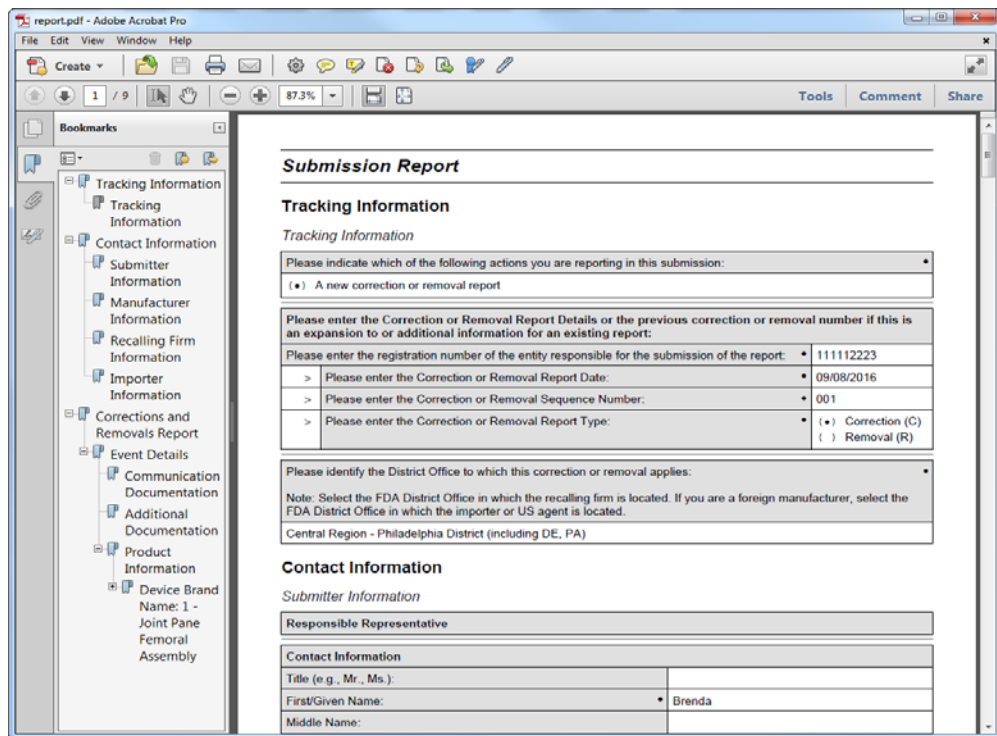
Step 22d: Use the previous button  to return to sections indicated in the report where information is missing. Enter the missing information and proceed to the next section by using the next button . All completed sections are represented by a check mark . Proceed to step 23a.




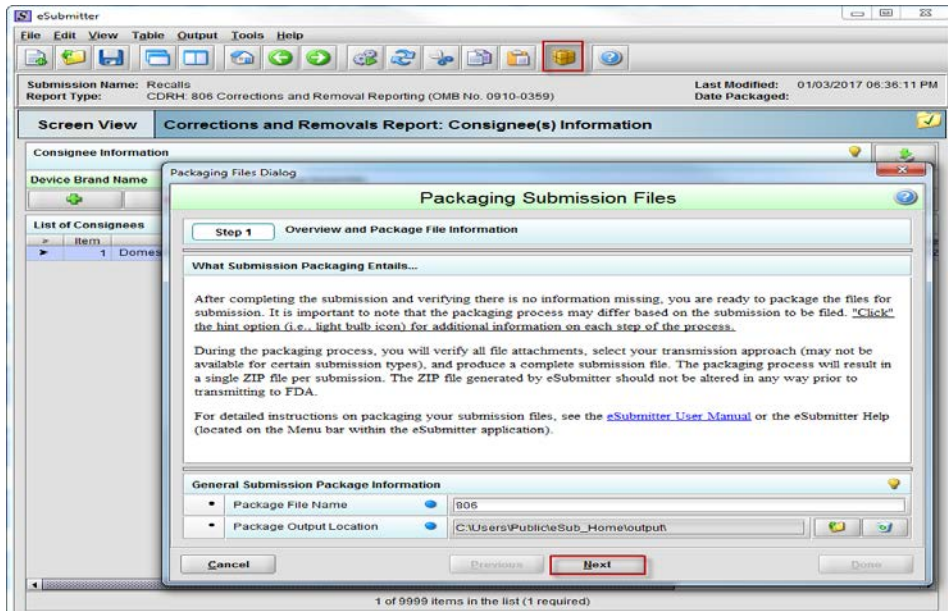
Step 23a: Click “Output” button to open drop down menu, select “Submission Report”. A Report Output Dialog box will appear. Ensure “System Default Viewer” is selected. Click “OK”. Proceed to step 23b.



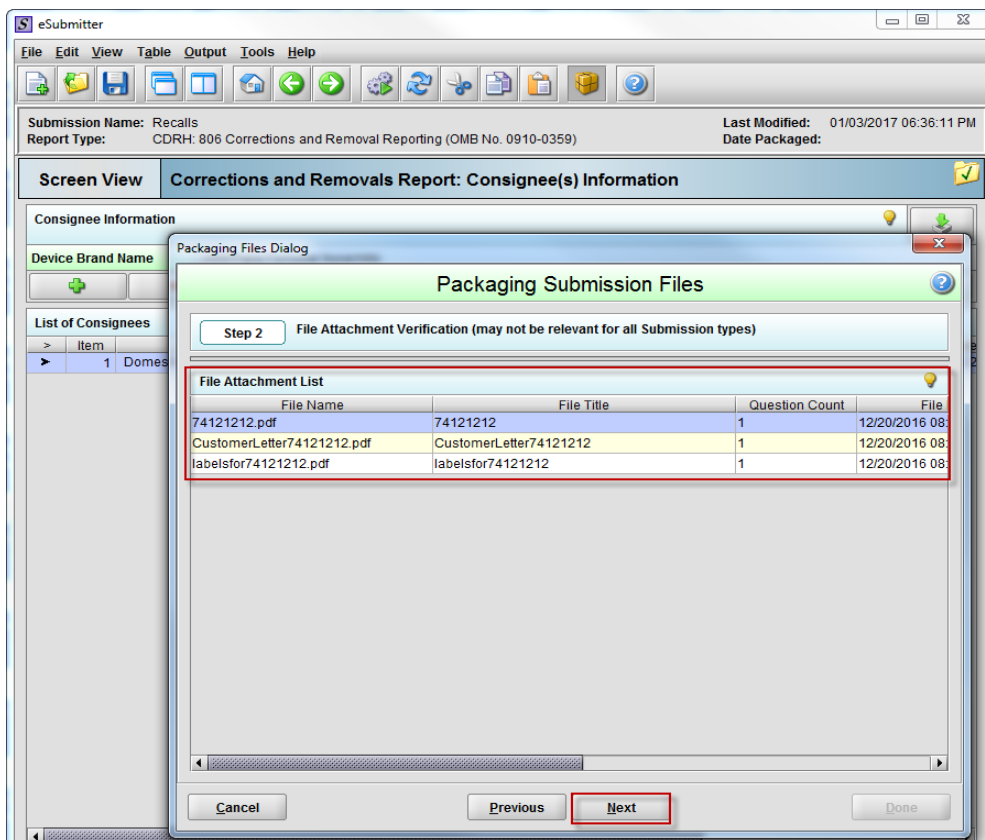
Step 23b: Review report for accuracy. If any information is incorrect, use the previous button  to go to the section/s and make the corrections. Proceed to step 24.



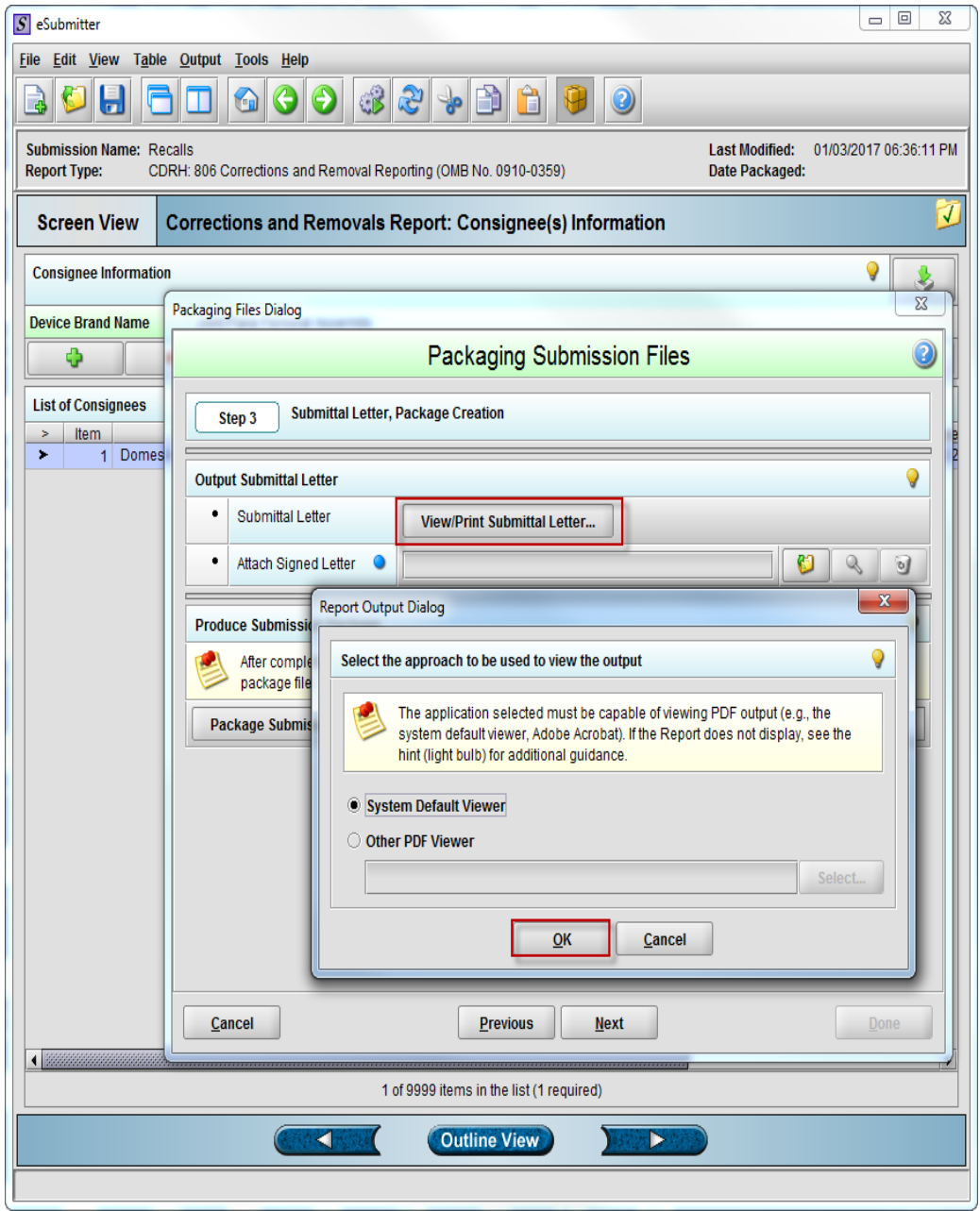
Step 24: Click on the “Package” button . A Packaging Files Dialog pop up box will appear. Read the Overview and Package File Information. Click “Next” and proceed to step 25.



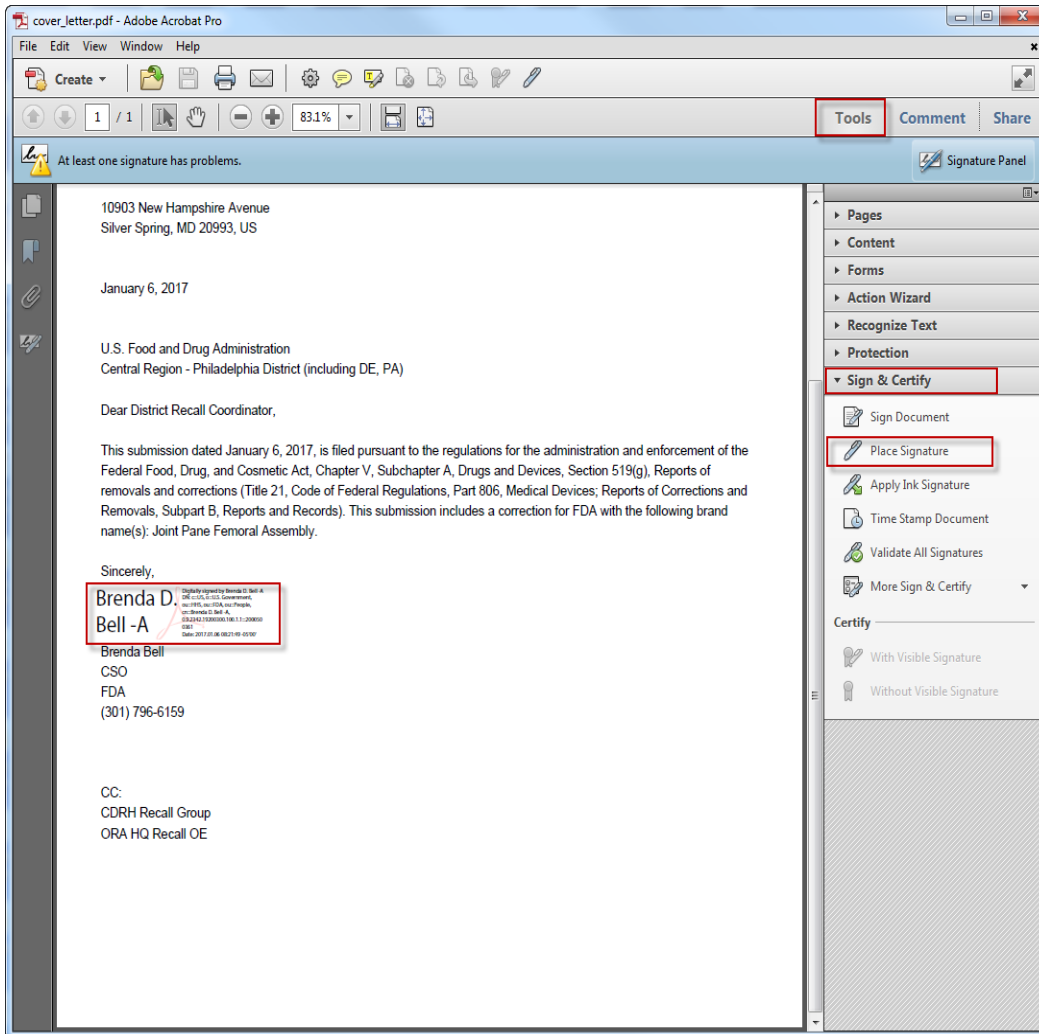
Step 25: Verify the file attachment(s) are correct. Click “Next” and proceed to step 26a.




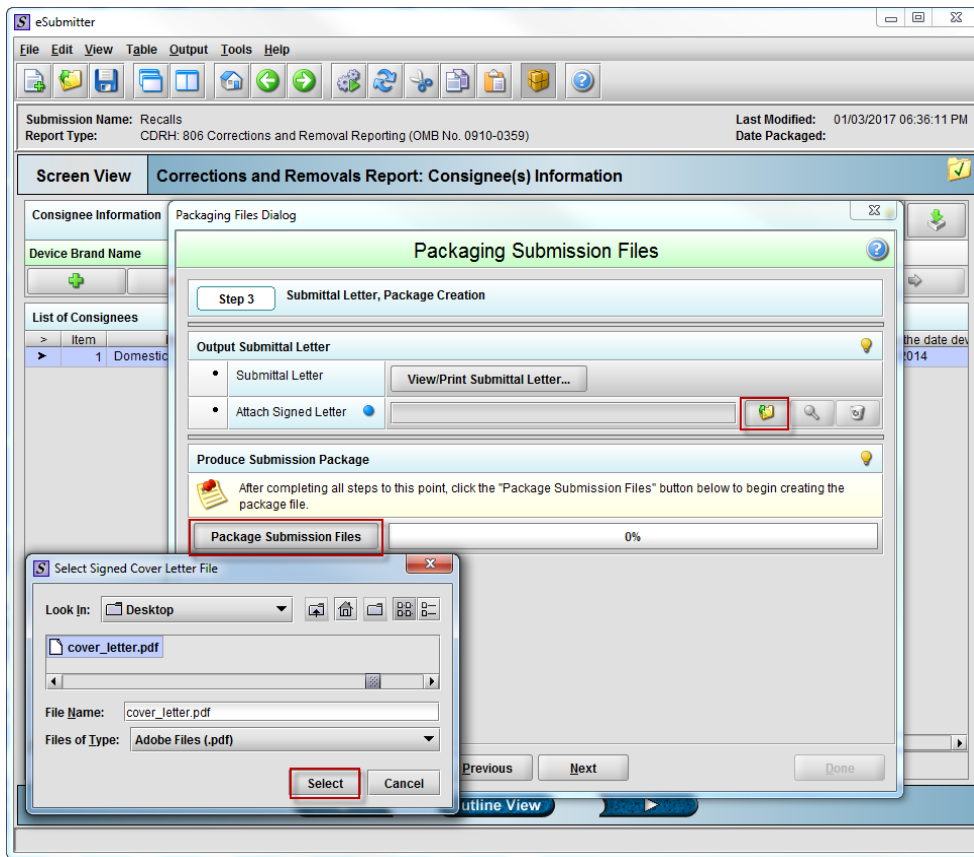
Step 26a: Create a signed letter. Click “View/Print Submitter Letter”. A Report Output Dialog pop up box will appear. Read the information and then click “OK”. Proceed to step 26b.



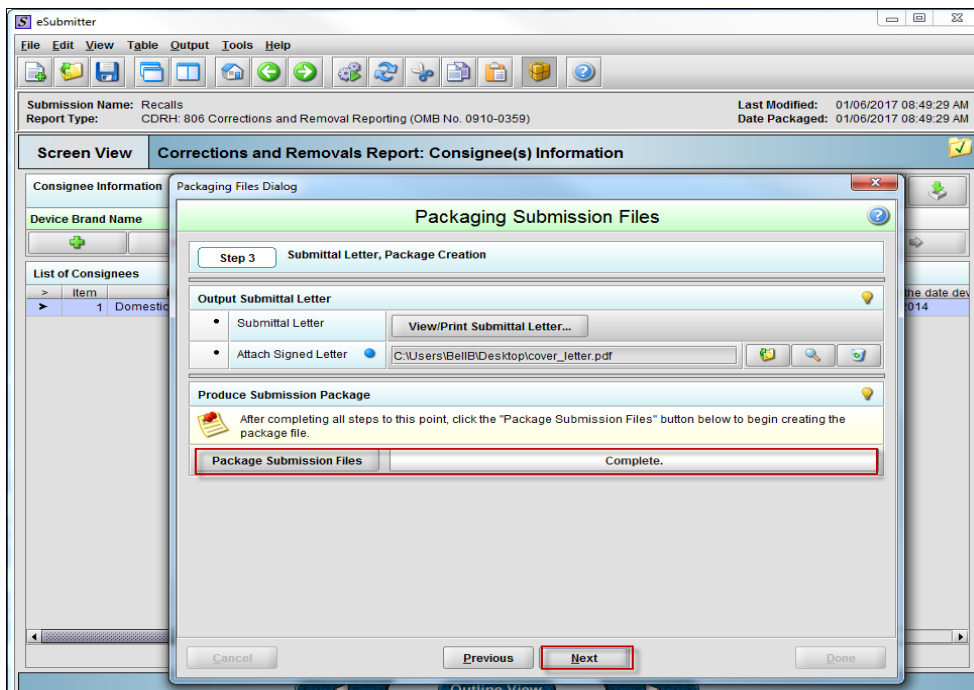
Step 26b: A copy of the letter appears. Click “Tools,” click “Sign & Certify,” click “Place Signature.” Use your cursor to add your signature. Click “OK” and save the letter on your desktop. Proceed to step 27.



Step 27: To attach the signed letter, click on the attach button  to open the “Select Signed Cover Letter File” pop up box. Retrieve the stored file. Click “Select” and then click “Package Submission Files.” Proceed to step 28.



Step 28: When packaging is complete, click “Next”. Proceed to step 29.



Step 29: A “Packaging Files Dialog” pop up box will appear. You have successfully created your submission package. Follow the Submission Package Transmission Instructions to transmit the submission. Click “Done”.

