

Electronic Submission of 806 Reports of Corrections and Removals

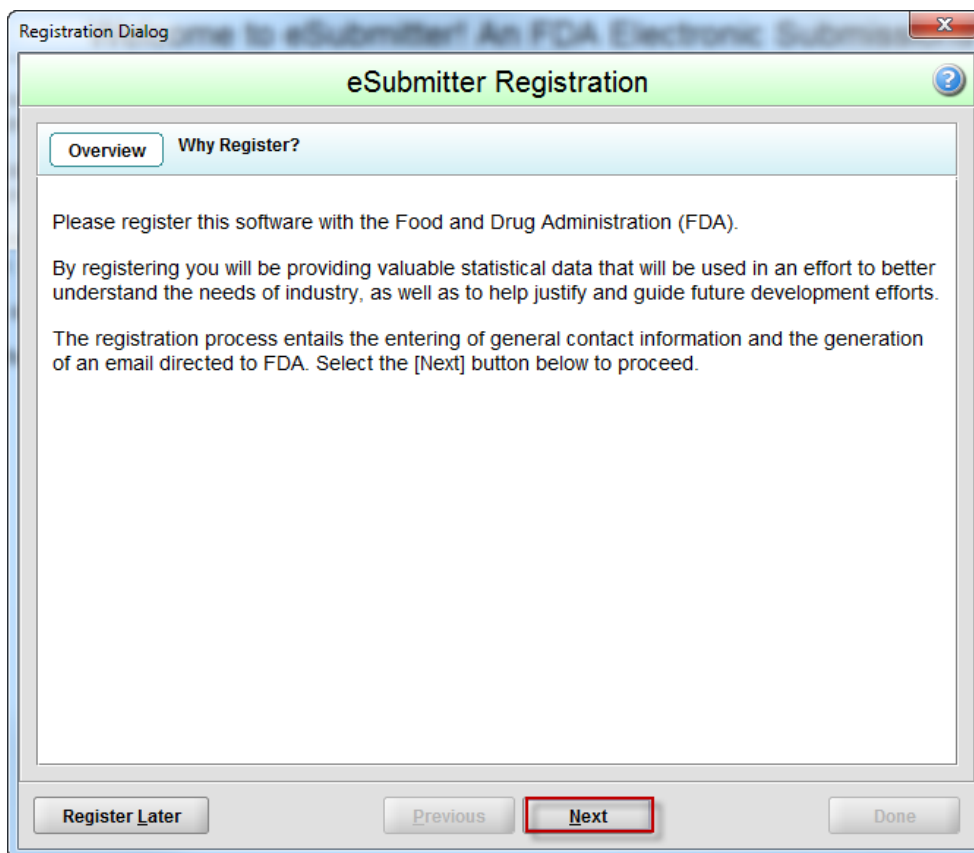
This tutorial provides instructions for completing Center for Devices and Radiological Health's (CDRH's) electronic submission of Medical Devices Corrections and Removals Reports.

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

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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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.

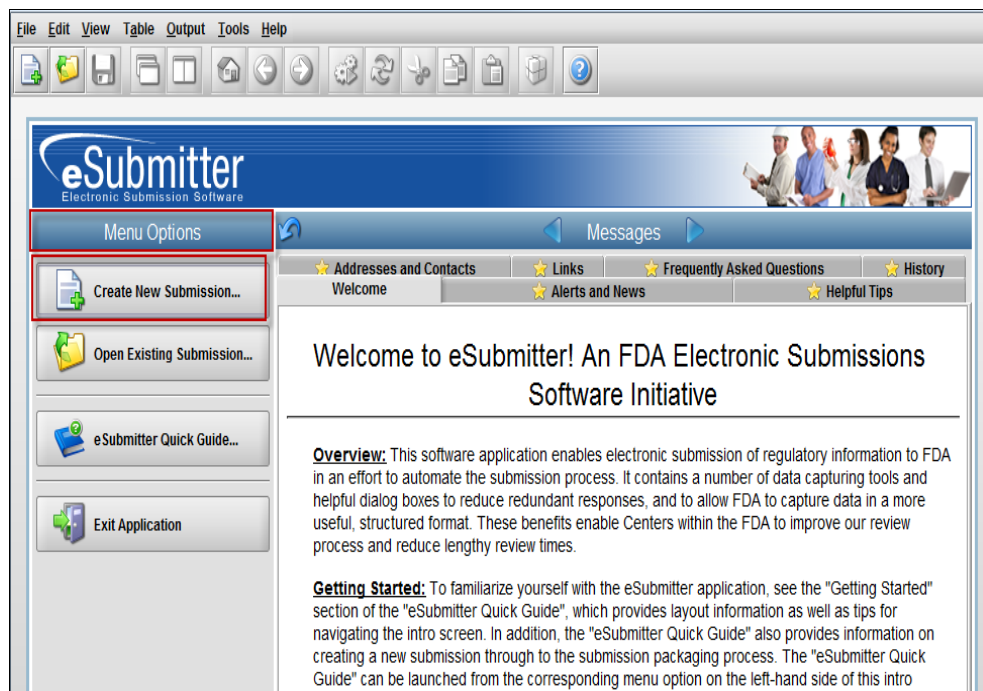


Use "left" arrow to move back to the previous page.

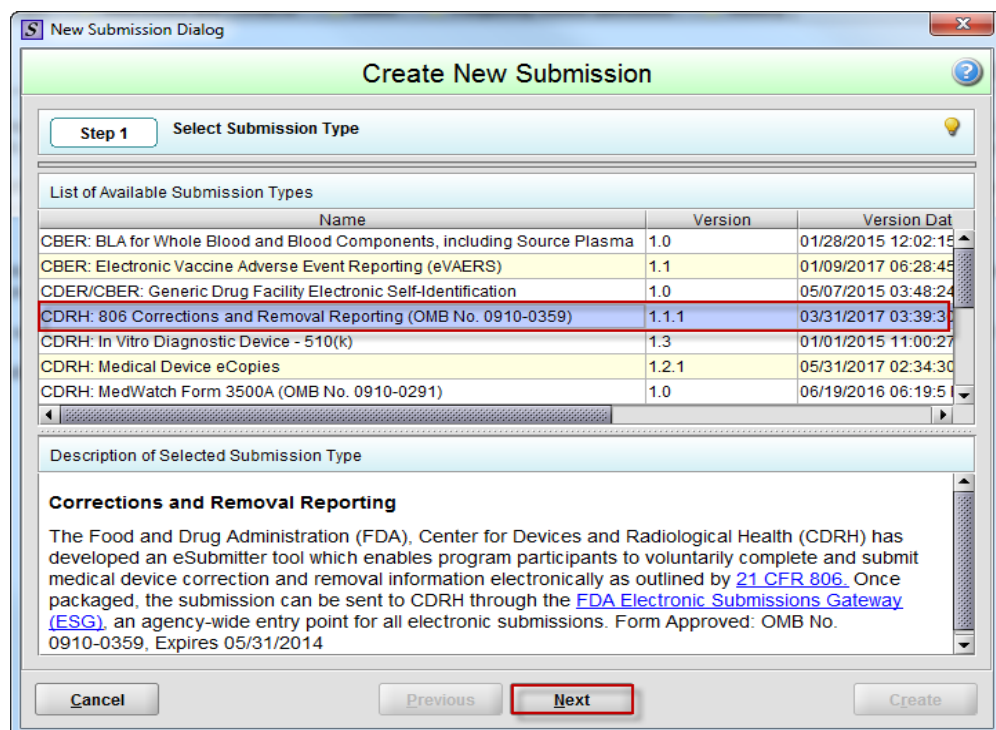
Note: All information requested by eSubmitter is necessary to complete the recall package (even if it is not per 21 CFR 806 reporting requirements). For example:

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"/>
<input type="checkbox"/> Method of Notification - Other	<input type="text"/>

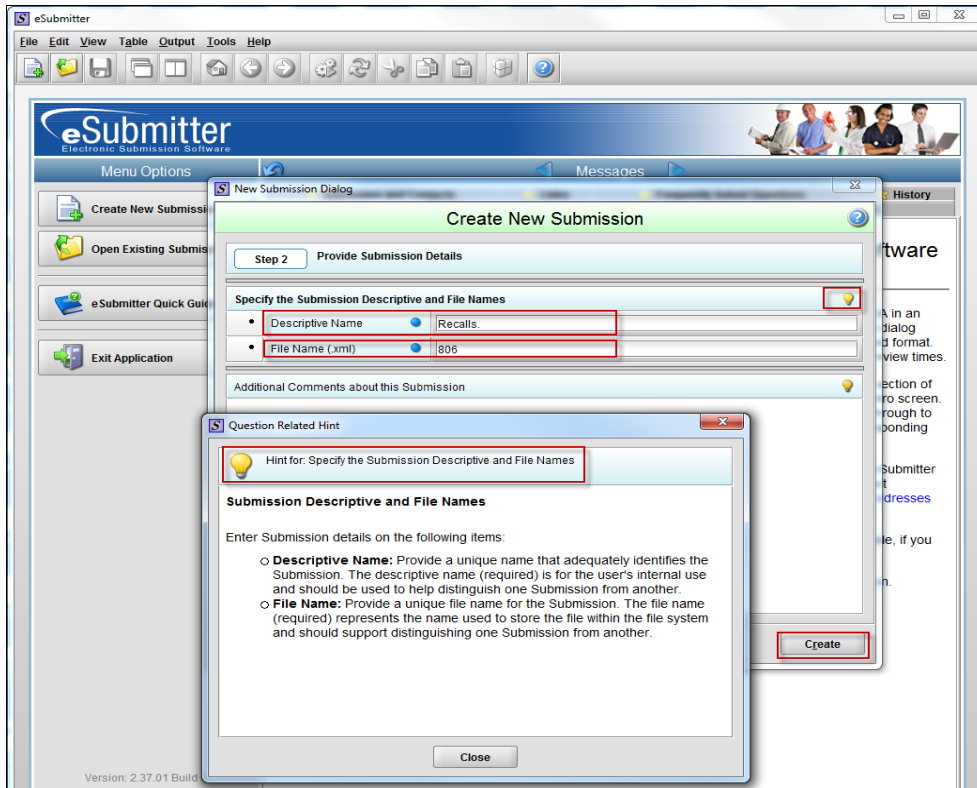
Step 5b: Creating a Medical Device Corrections and Removals Report--under “Menu Options”, click “Create New Submission.” Proceed to step 6.



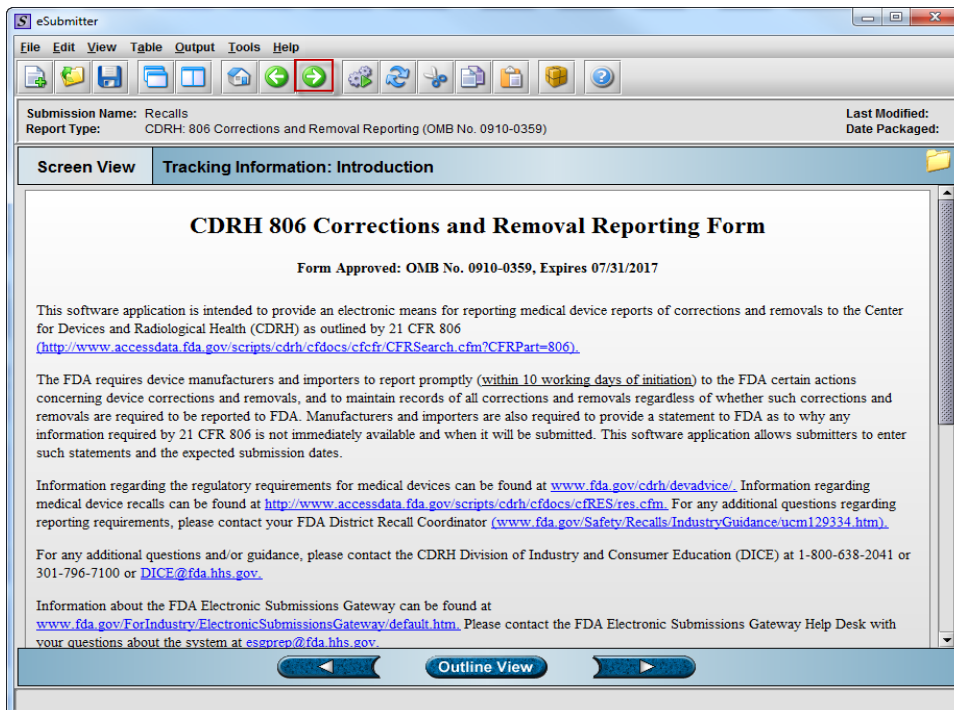
Step 6: When the New Submission Dialog pop up box appears, choose submission type: CDRH: 806 Corrections and Removals Reporting. Click “Next” and proceed to step 7.



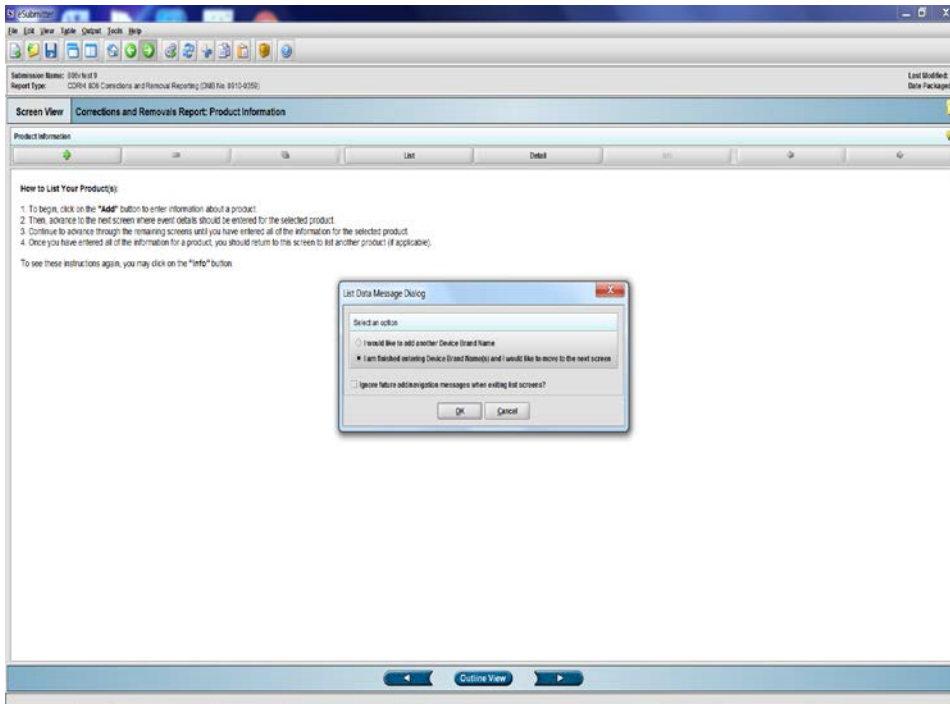
Step 7: Provide Submission Details. Enter Descriptive and File names. Provide any additional information about the submission as needed. Click “Create.” Option: If you need assistance, click the light bulb for help on how to enter the information. Proceed to step 8a.



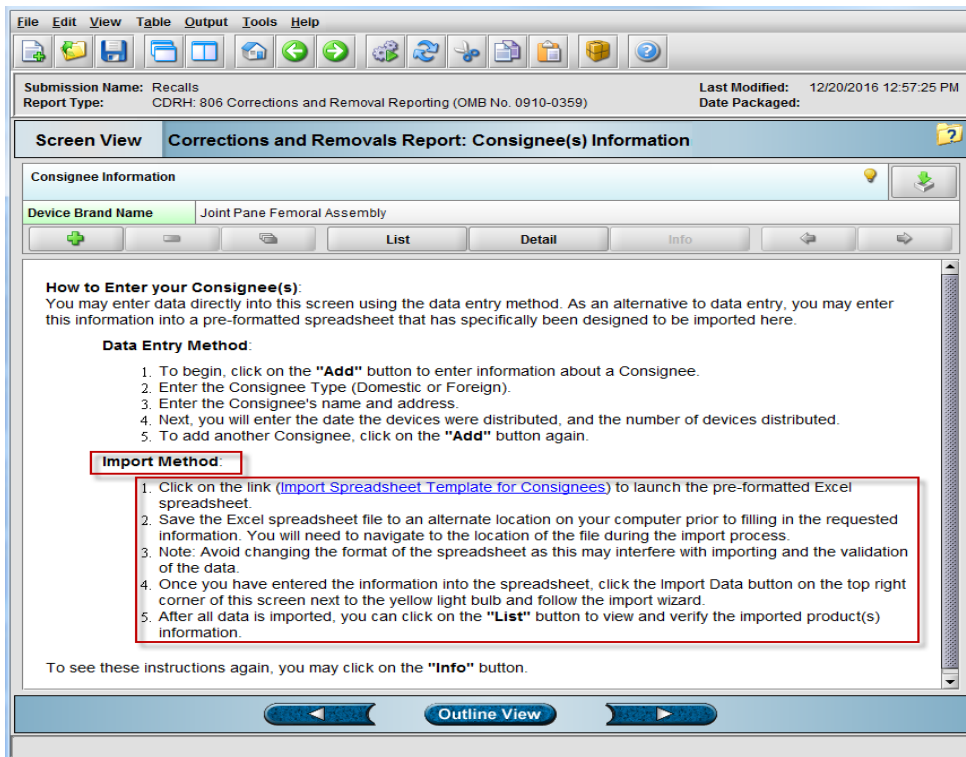
Step 8a: If this is your first time using eSubmitter for 806 reporting, read the CDRH 806 Corrections and Removals Reporting Form information. Click the “Next” arrow until you see the **Consignee Information** screen. Then proceed to Step 8b for instructions to download the Excel spreadsheet. If you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




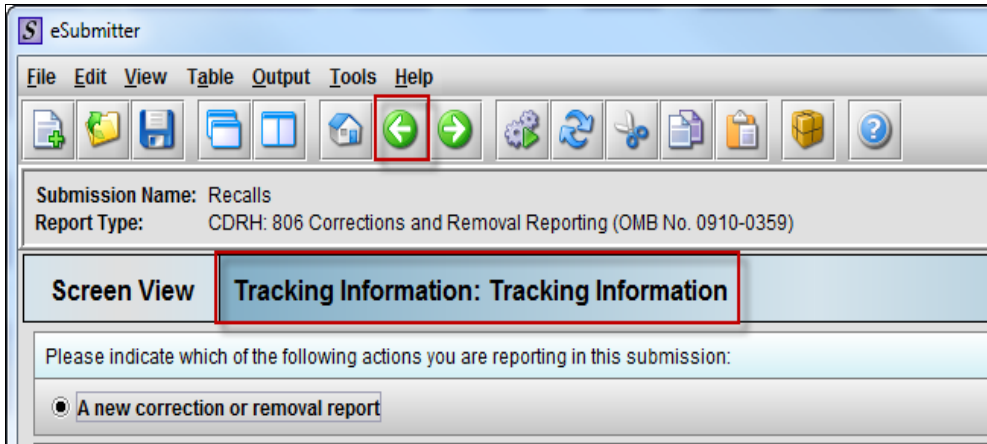
Click on "OK" button to proceed to the **Consignee Information** screen



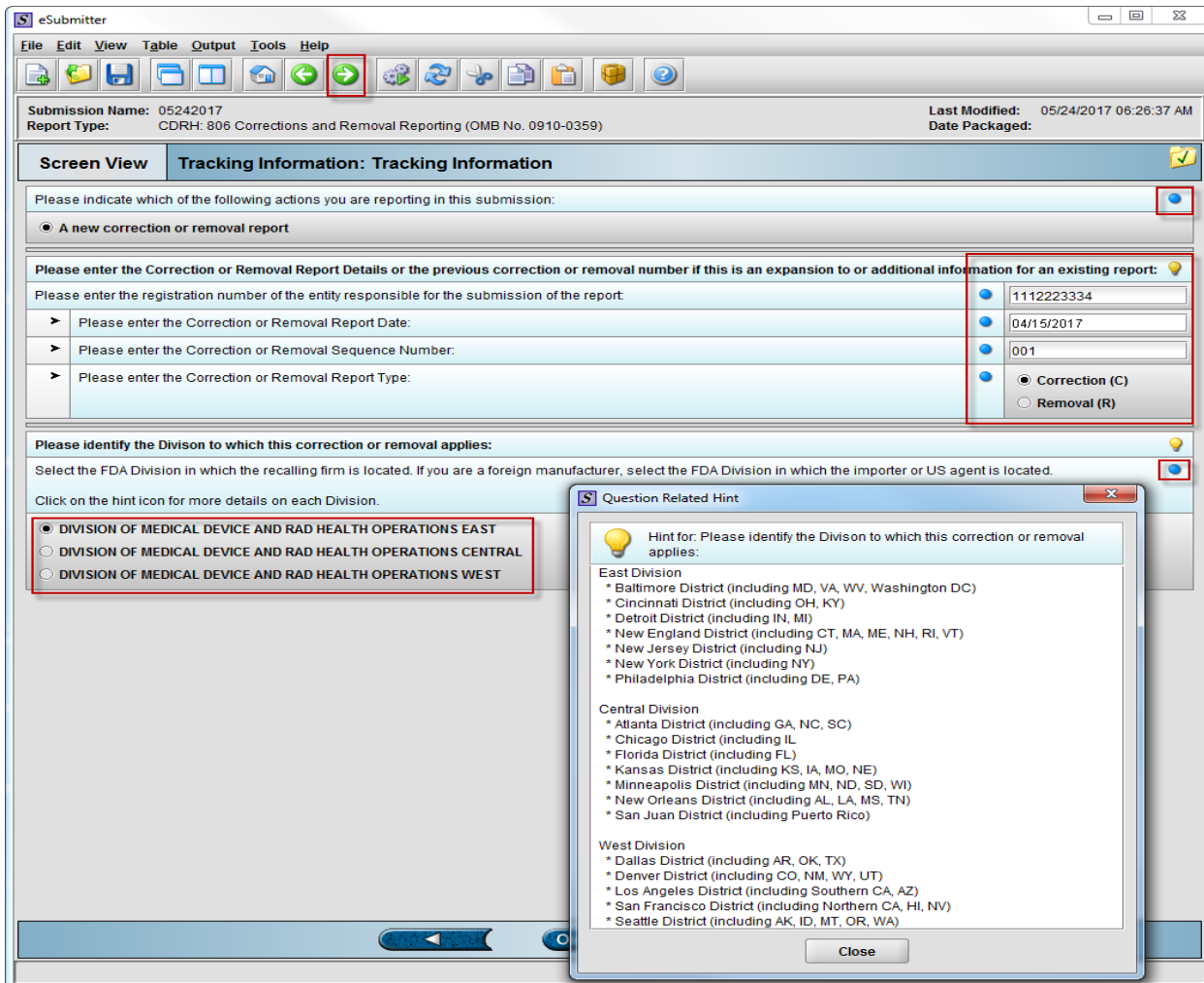
Step 8b: Review and follow the Import Method instructions on the Consignee Information screen. Remember to save the pre-formatted Excel spreadsheet to your desktop. Complete the required fields on the spreadsheet. Use this spreadsheet to enter your consignee information into eSubmitter. You can use this 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
Report Type: CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)

Last Modified: 12/12/2016 08:47:41 PM
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

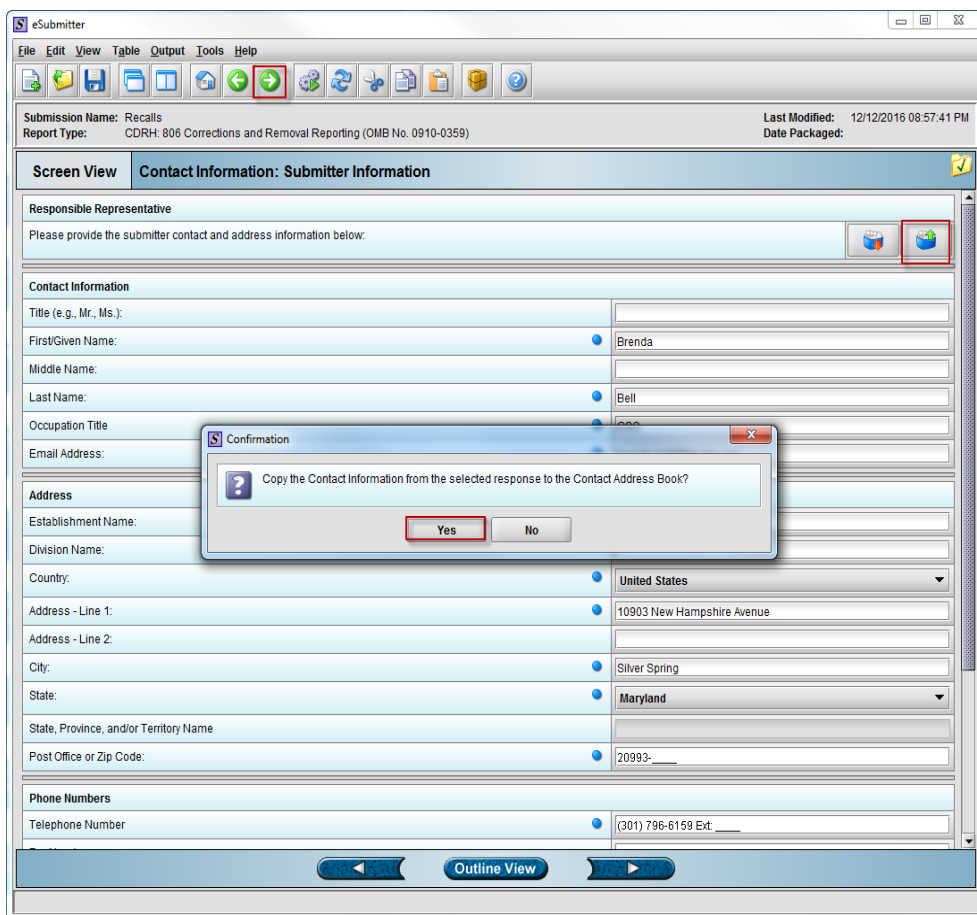
Establishment Name:	FDA
Division Name:	
Country:	United States
Address - Line 1:	10903 New Hampshire Avenue
Address - Line 2:	
City:	Silver Spring
State:	Maryland
State, Province, and/or Territory Name:	
Post Office or Zip Code:	20993-____

Phone Numbers

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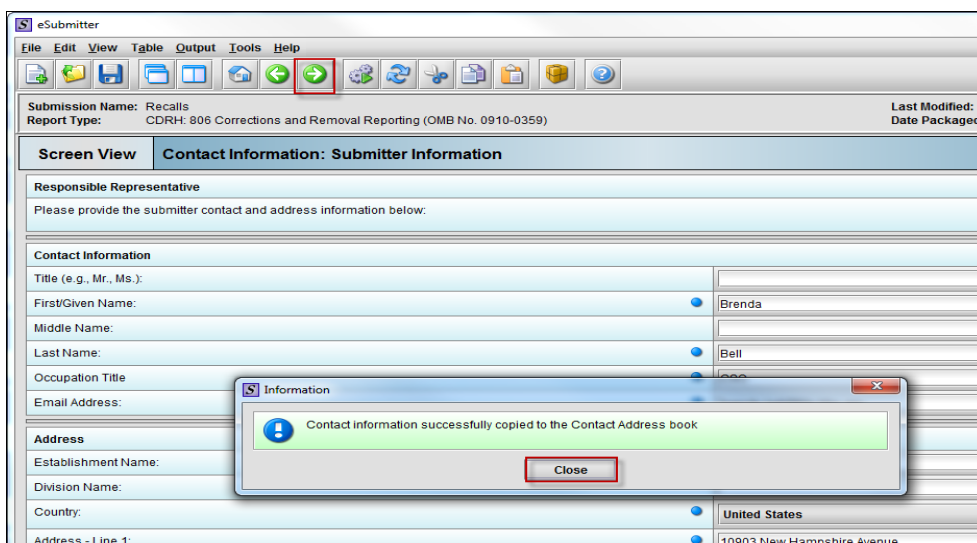
Outline View

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.



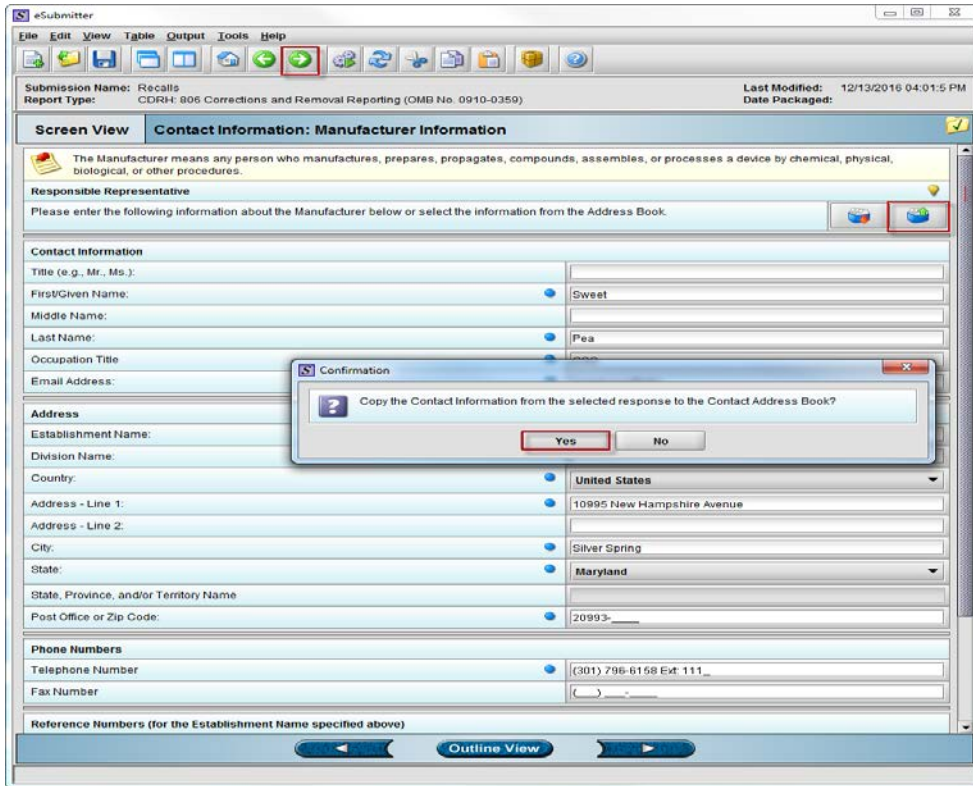
The screenshot shows the eSubmitter application window. The main form is titled "Contact Information: Submitter Information" and contains several sections: "Responsible Representative", "Contact Information", "Address", and "Phone Numbers". The "Contact Information" section includes fields for Title, 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 dialog box has "Yes" and "No" buttons. The "Next" arrow button at the bottom of the form is 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.

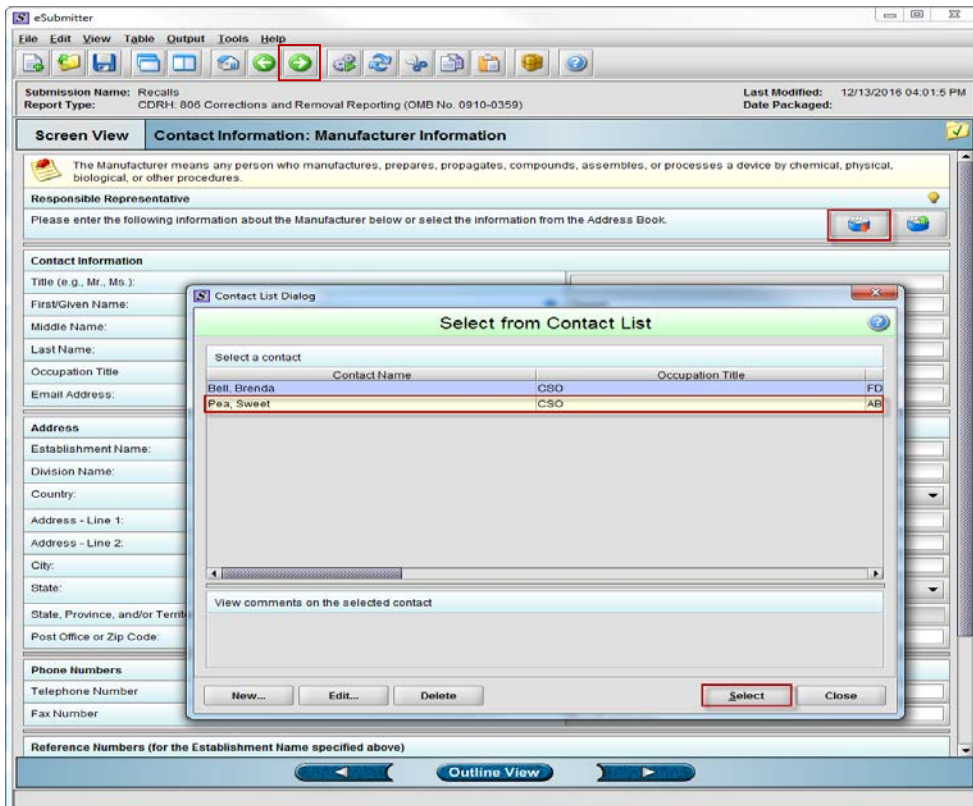



The screenshot shows the eSubmitter application window, similar to the previous one. The main form is titled "Contact Information: Submitter Information". An "Information" dialog box is overlaid on the form, displaying a blue information icon and the text "Contact information successfully copied to the Contact Address book". The dialog box has a "Close" button. The "Next" arrow button at the bottom of the form is highlighted with a red box.

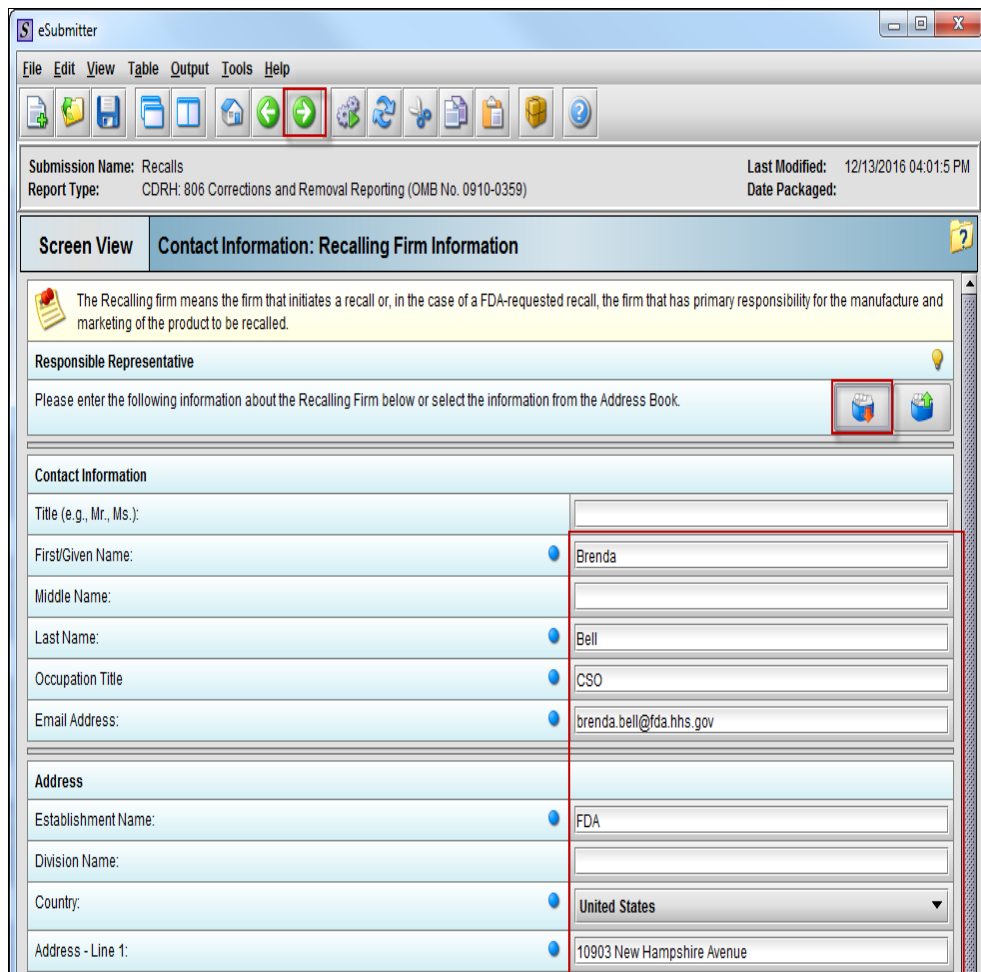
Step 13a: Enter “Manufacturer Information” if different from previously saved information. Repeat step 11.



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.



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

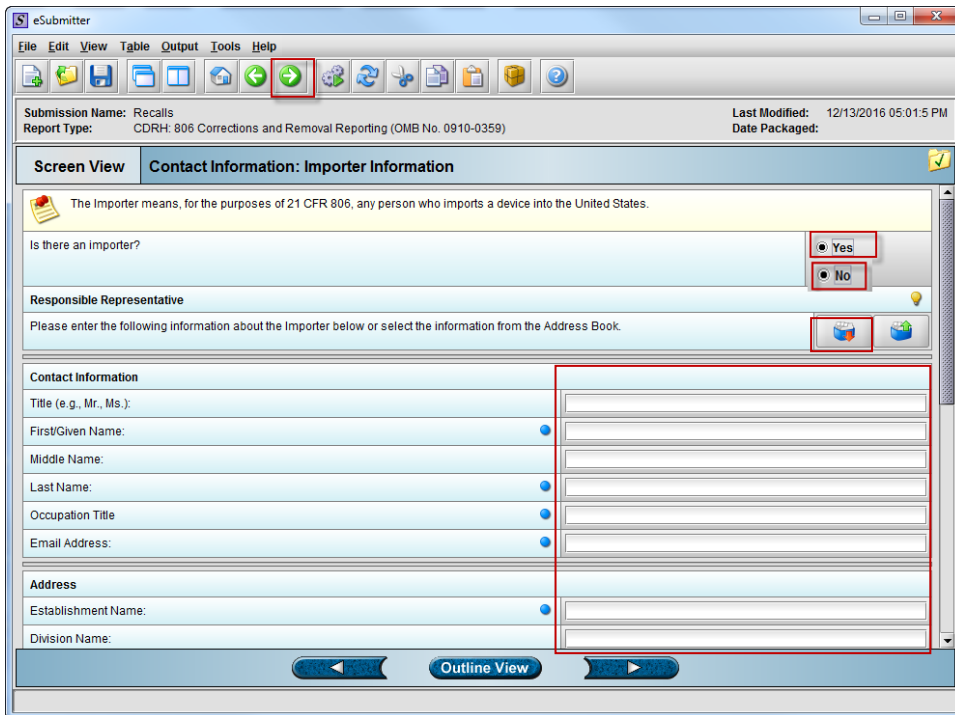
Establishment Name:	FDA
Division Name:	
Country:	United States
Address - Line 1:	10903 New Hampshire Avenue

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'. It 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 (highlighted with a red box) and an 'Address Book' icon. Below this are sections for 'Contact Information' and 'Address', each with several text input fields. At the bottom, there are navigation buttons: a left arrow, 'Outline View', and a right arrow.

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

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 arrow icon highlighted. The main content area is titled "Screen View Corrections and Removals Report: Event Details". It contains several sections:

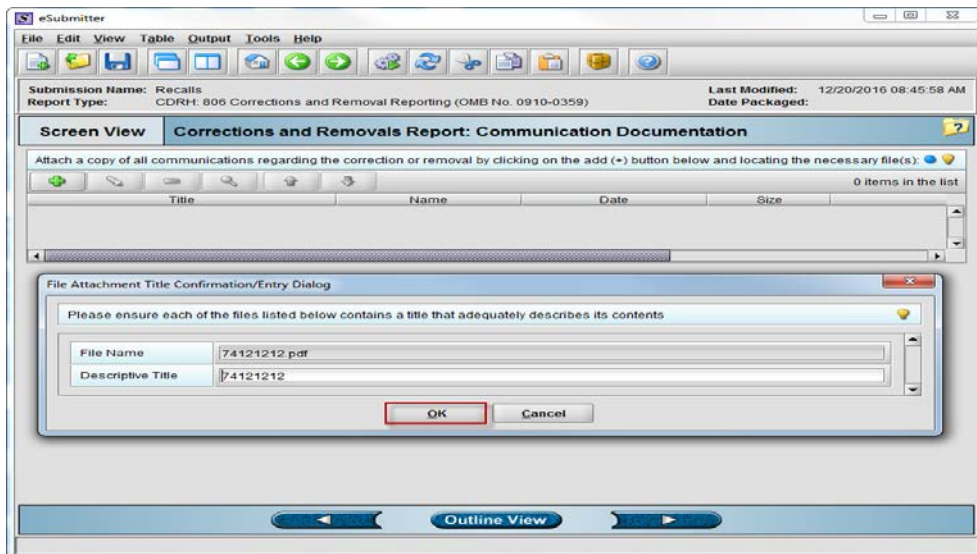
- A dropdown menu with the text: "Please select the regulatory violation being reported in this correction or removal:"
- Form fields for:
 - Firm Awareness Date: 04/09/2016
 - Recall Initiation Date: 04/11/2016
 - Method of Notification: Letter
 - Method of Notification - Other: (empty)
- A text area with the prompt: "Please describe the event(s) giving rise to the information reported:" and the text: "The expected surface roughness of the femoral component is out of specification".
- A text area with the prompt: "Please describe any corrective or removal actions that have been, and are expected to be taken:" and the text: "Field Safety Notice describing actions to be taken by consignees. Products will be reworked".
- A text area with the prompt: "Please describe any illness or injuries that have occurred with the use of the device(s):" and the text: "None reported".

At the bottom, there are navigation buttons: a left arrow, "Outline View", and a right arrow.

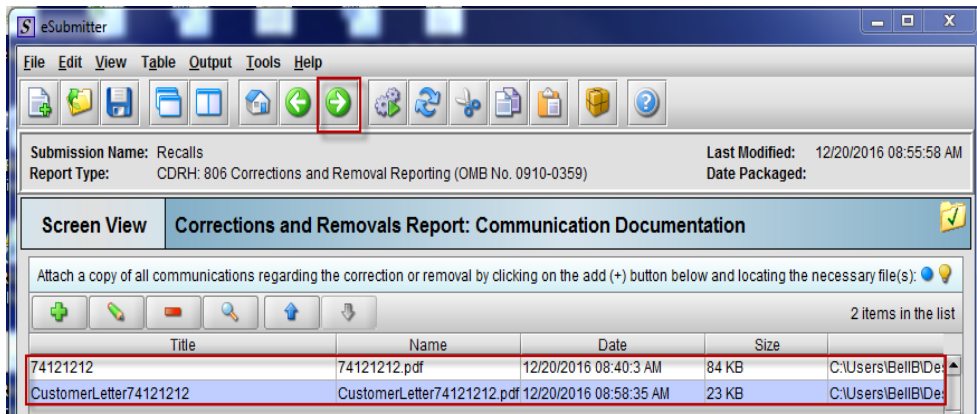
Step 17a: Attach a copy of all communication documents by clicking on the add button . When the pop up box appears, select the file from your computer. Click “Select” and proceed to step 17b.


The screenshot shows the eSubmitter application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The main content area is titled "Screen View Corrections and Removals Report: Communication Documentation". It contains a section with the prompt: "Attach a copy of all communications regarding the correction or removal by clicking on the add (+) button below and locating the necessary file(s):". A green plus button is highlighted. Below this is a table with columns: Title, Name, Date, Size, and a "0 items in the list" indicator. 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. The dialog box also shows the "File Name:" field containing "74121212.pdf" and the "Files of Type:" dropdown set to "All Supported File Types". The "Select" button is highlighted.

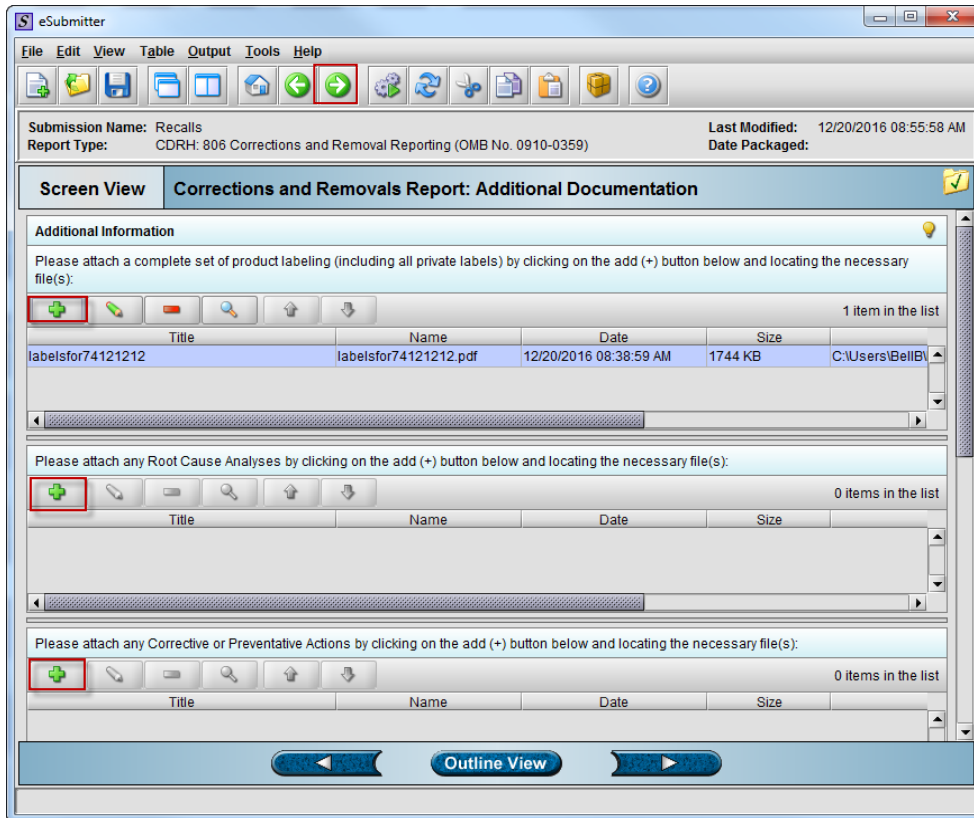
Step 17b: When the File Attachment Title Confirmation/Entry Dialog pop up box appears, click “OK.” Repeat the process until all desired documents are added. Proceed to step 17c.




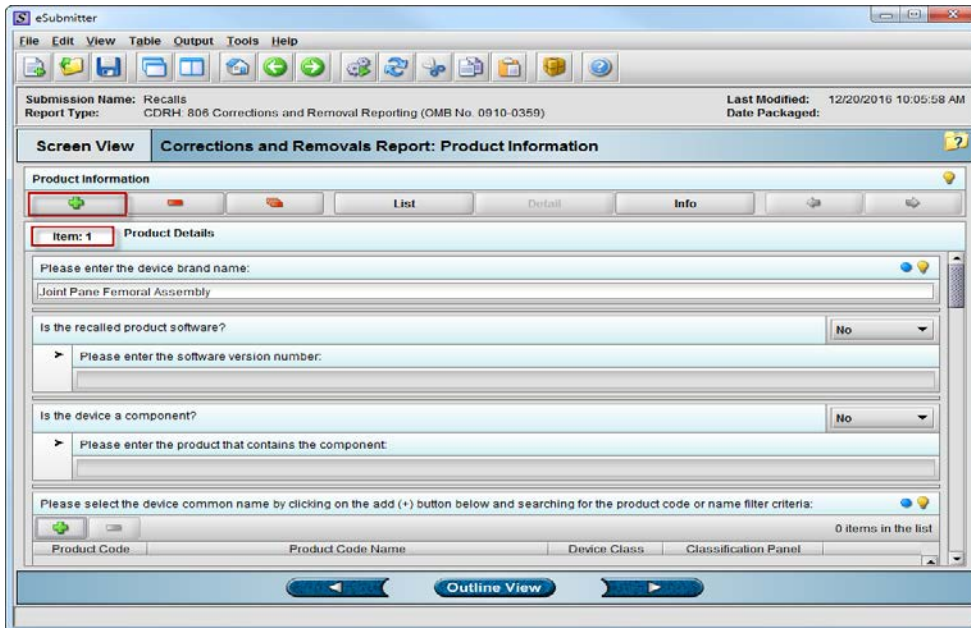
Step 17c: When all of your attached documents are listed, click the “Next” arrow. Proceed to step 18.



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.

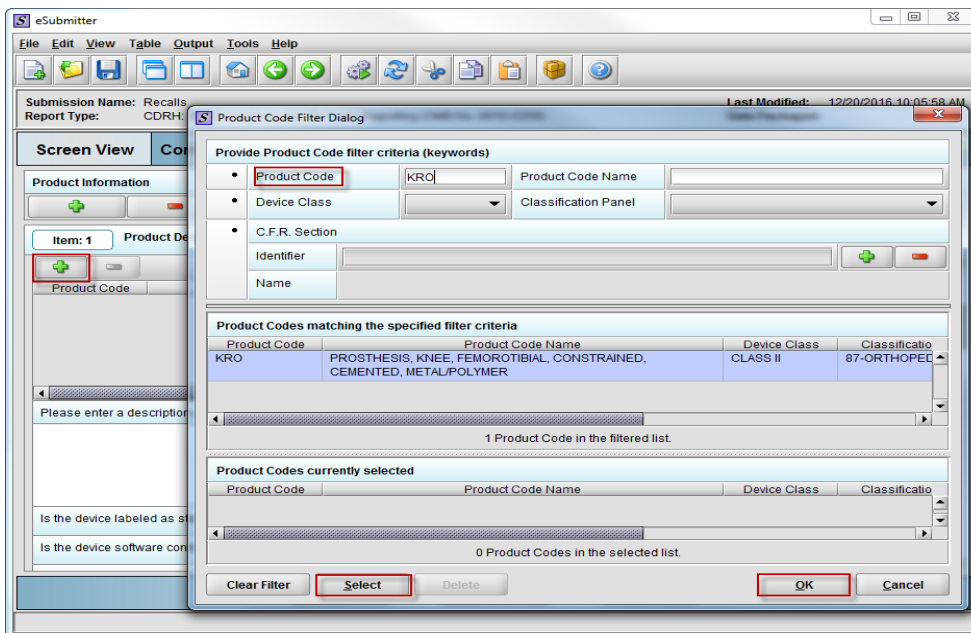


Step 19a: Provide the product information by clicking the add button . Each product will be identified by Item # (i.e. Item:1, 2, etc.). Enter the requested information by answering all of the questions for each item. Proceed to step 19b.



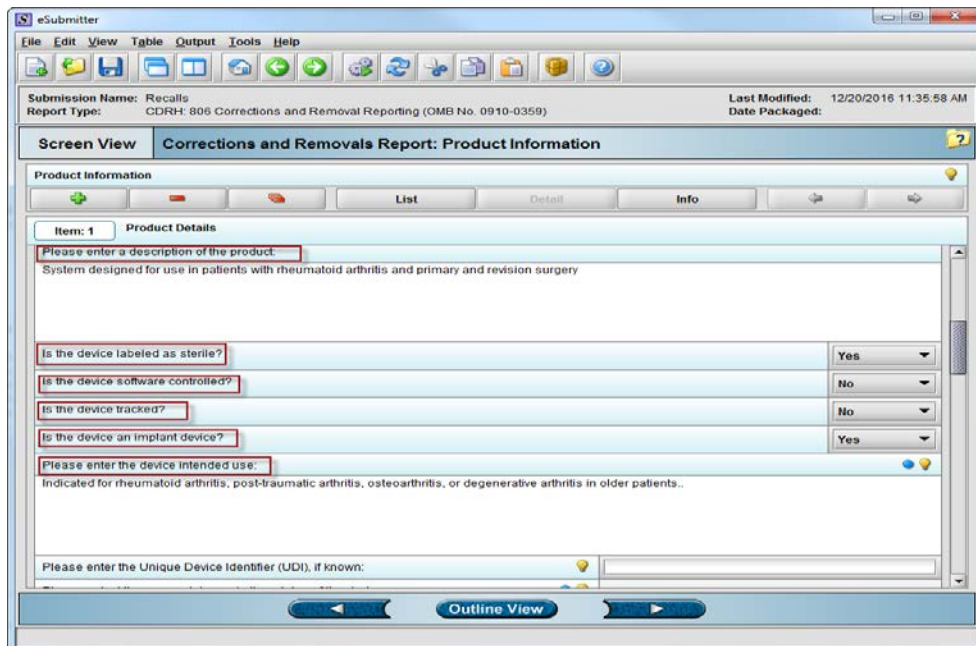
The screenshot shows the 'eSubmitter' application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The status bar at the top right shows 'Last Modified: 12/20/2016 10:05:58 AM' and 'Date Packaged:'. The main window title is 'Screen View Corrections and Removals Report: Product Information'. Below this, there is a 'Product Information' section with a toolbar containing an add button (highlighted with a red box), a minus button, a list button, a detail button, and an info button. The 'Item: 1' tab is active, showing 'Product Details'. The form contains several fields: 'Please enter the device brand name:' with the value 'Joint Pane Femoral Assembly'; 'Is the recalled product software?' with a dropdown set to 'No'; 'Please enter the software version number:'; 'Is the device a component?' with a dropdown set to 'No'; 'Please enter the product that contains the component:'. At the bottom, there is a section for 'Please select the device common name by clicking on the add (+) button below and searching for the product code or name filter criteria:'. This section includes an add button (highlighted with a red box) and a table with columns 'Product Code', 'Product Code Name', 'Device Class', and 'Classification Panel'. The table is currently empty, showing '0 items in the list'. At the bottom of the window, there is an 'Outline View' button.

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.

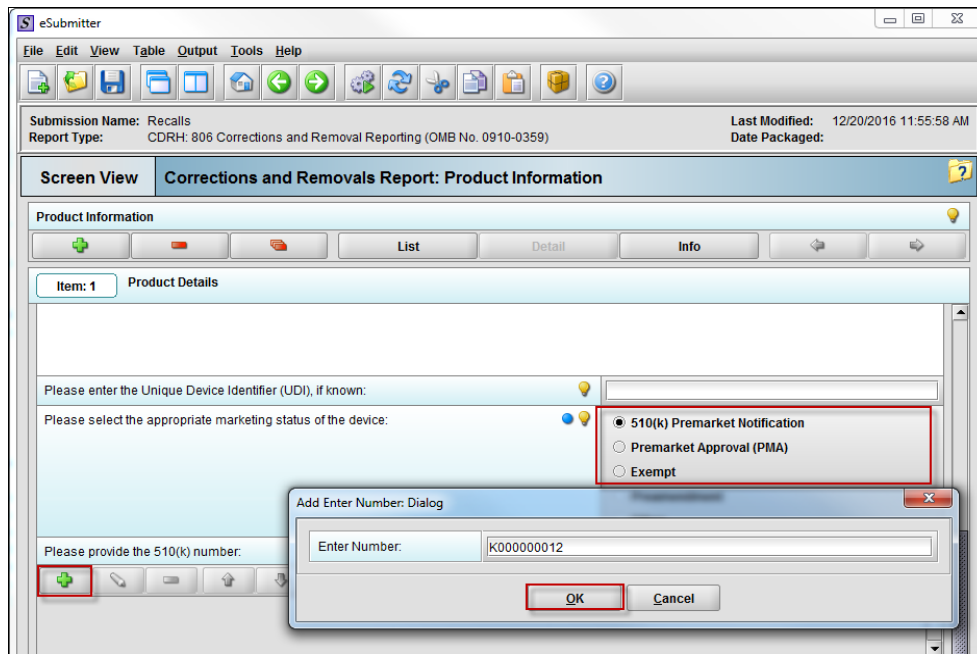


The screenshot shows the 'eSubmitter' application window with the 'Product Code Filter Dialog' open. The dialog has a title bar 'Product Code Filter Dialog' and a close button. It contains several sections: 'Provide Product Code filter criteria (keywords)' with three criteria: 'Product Code' (with a text field containing 'KRO'), 'Device Class' (with a dropdown), and 'C.F.R. Section' (with a text field and an add button). Below this is a table titled 'Product Codes matching the specified filter criteria' with columns 'Product Code', 'Product Code Name', 'Device Class', and 'Classification Panel'. The table contains one row: 'KRO', 'PROSTHESIS, KNEE, FEMOROTIBIAL, CONSTRAINED, CEMENTED, METAL/POLYMER', 'CLASS II', and '87-ORTHOPE'. Below the table, it says '1 Product Code in the filtered list'. At the bottom, there is a section titled 'Product Codes currently selected' with a table that is currently empty, showing '0 Product Codes in the selected list'. The dialog has four buttons at the bottom: 'Clear Filter', 'Select' (highlighted with a red box), 'Delete', 'OK' (highlighted with a red box), and 'Cancel'.

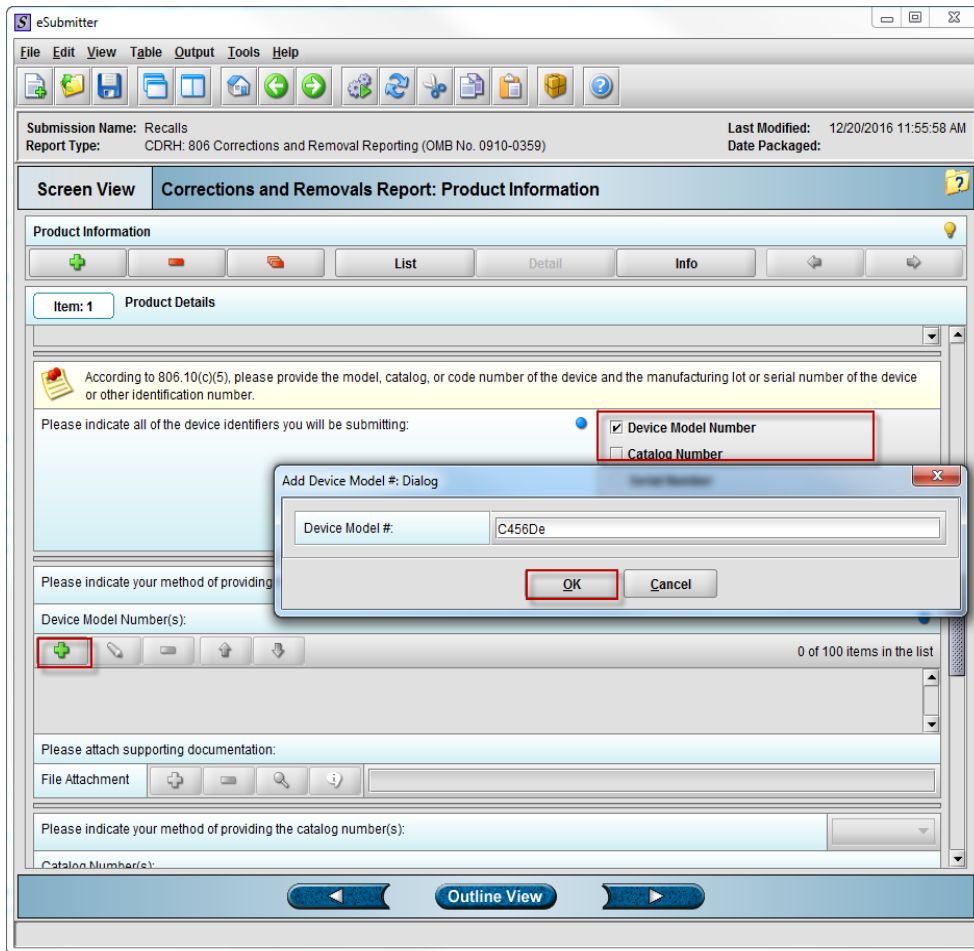
Step 19c: Continue to enter the product information. Proceed to step 19d.



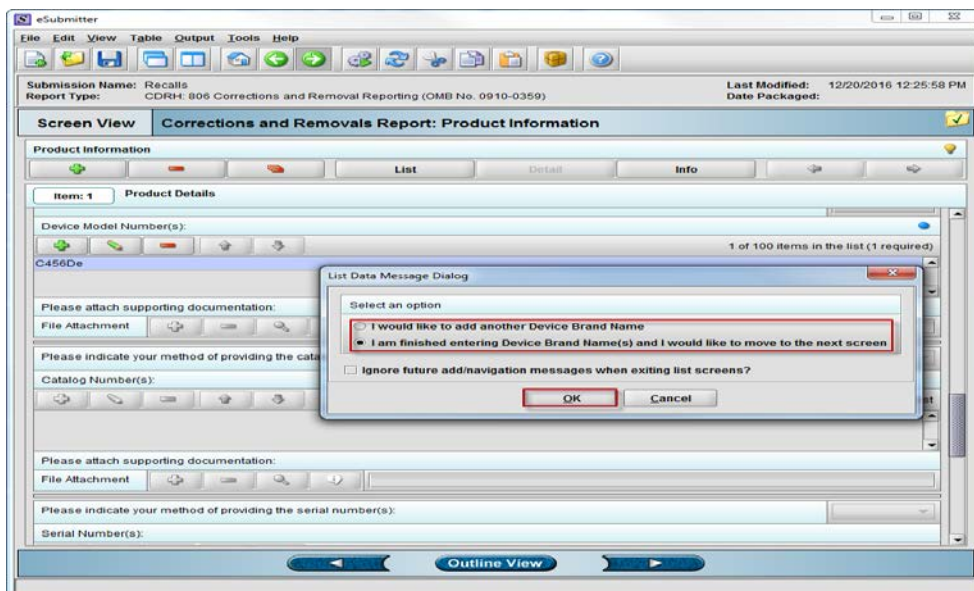
Step 19d: Add the marketing status of the device. Provide the application number, if applicable, by clicking on the button. Proceed to step 19e.



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 Corrections and Removals Report: Correction or Removal Product Details". Under "Device Brand Name", the value "Joint Pane Femoral Assembly" is shown. The data entry section contains several fields, each with a lightbulb icon: "Please enter the total number of devices manufactured subject to the correction or removal:" with the value "5789"; "Please enter the date range of manufacture:" with the range "01/20/2016 to 01/22/2016"; "Please enter the total number of devices distributed subject to the correction or removal:" with the value "700"; "Please enter the date range of distribution:" with the range "03/22/2016 to 03/22/2016"; "Please enter the total number in the same batch, lot or equivalent unit of production:" with the value "500"; "Please select the device expiration or expected end of life date format:" with a dropdown menu set to "Text Format"; "Please enter the device expiration date or expected end of life date:" with a date field; and "Please describe the device expiration date or expected end of life date:" with a text area containing "shelf life of 7 years". A red box highlights the dropdown menu and the date field.

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

eSubmitter

File Edit View Table Output Tools Help

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: 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.

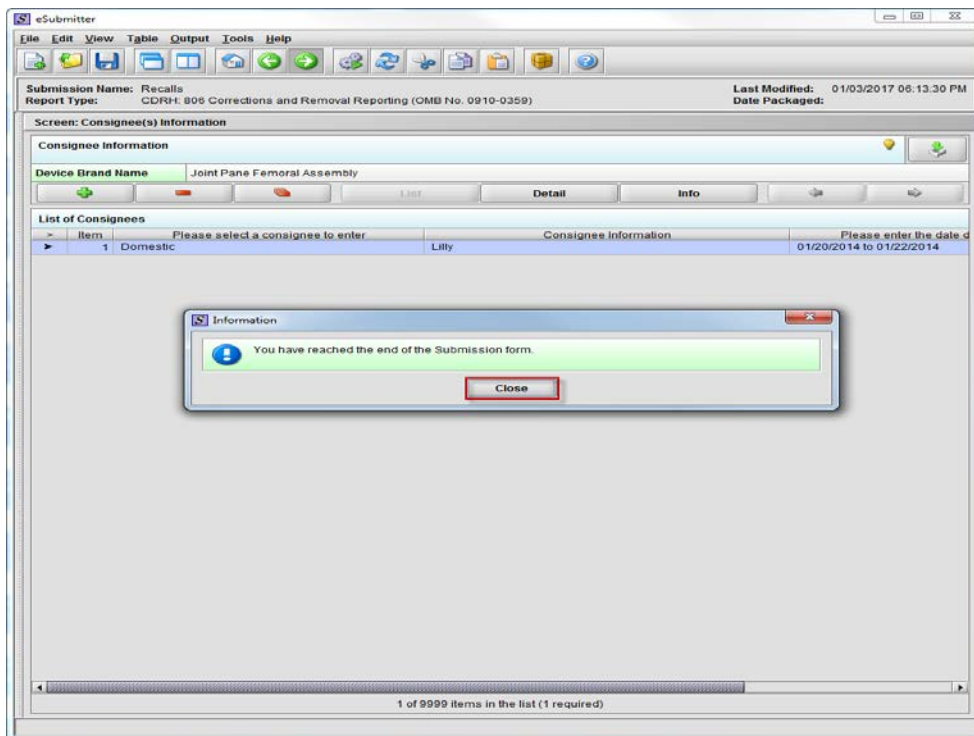
Import Method:

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.

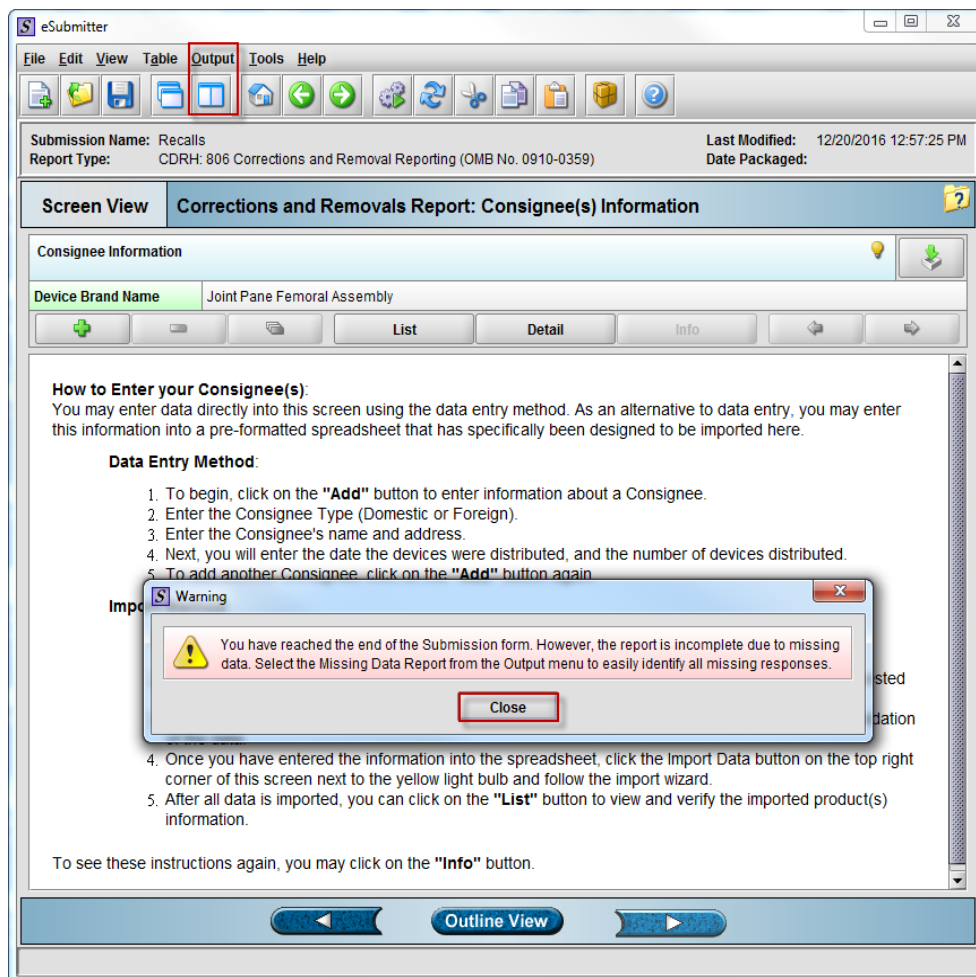
To see these instructions again, you may click on the "Info" button.



Outline View

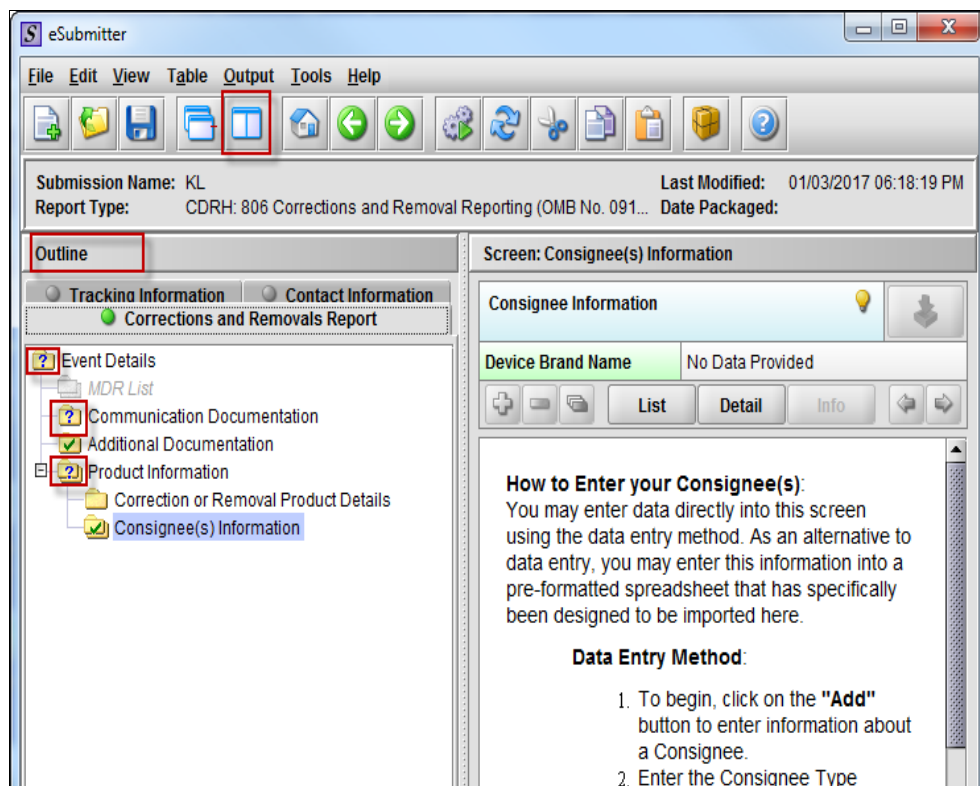
Step 22a: If an “Information” pop up box stating “You have reached the end of the submission form” appears, your report is complete. Close the information pop up box. Proceed to step 23a. If a “Warning” pop up box appears, proceed to step 22b.






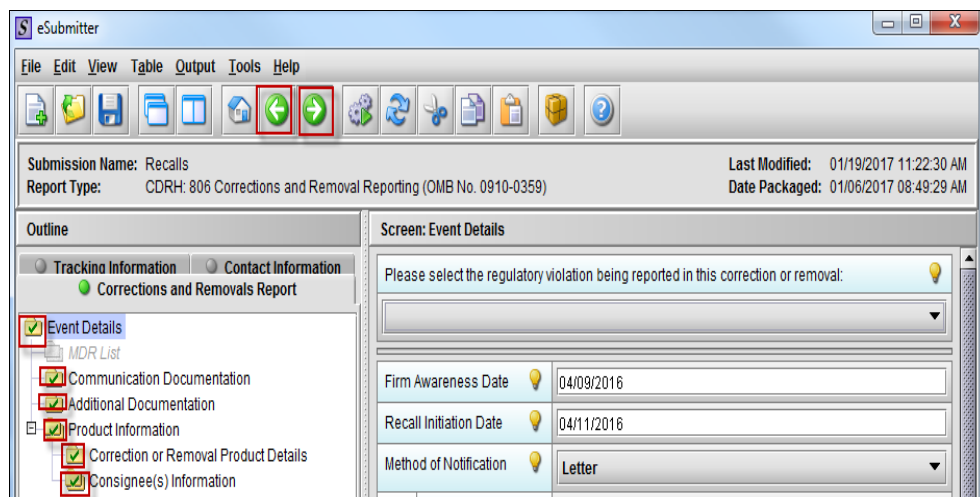
Step 22b: If a “Warning” pop up box stating “**You have reach the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses,**” click “Close” and proceed to step 22c.



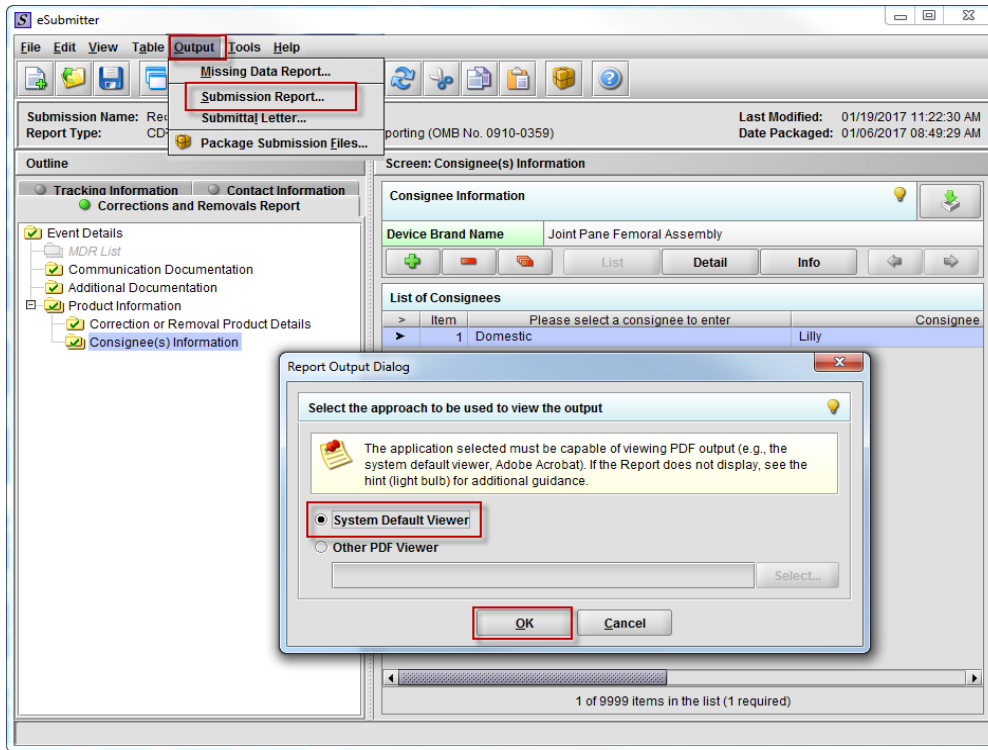
Step 22c: From the Menu Bar, click on the “Output” button . An outline of the sections where data is missing appears to the left of the screen and is represented by a question mark . Proceed to step 22d.




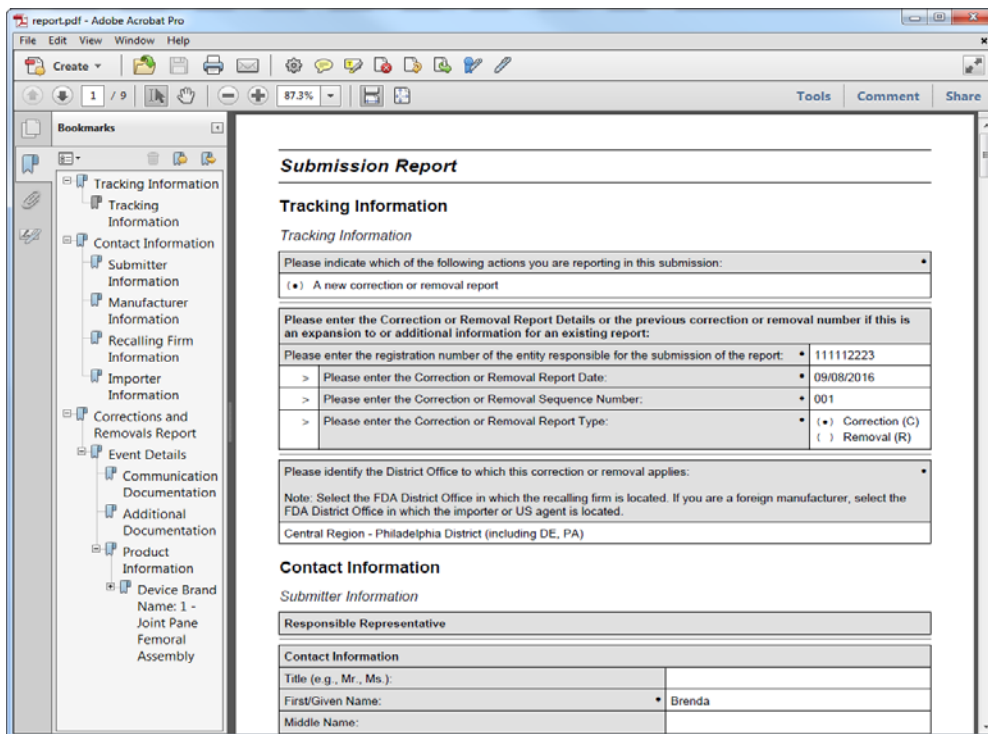
Step 22d: Use the previous button  to return to sections indicated in the report where information is missing. Enter the missing information and proceed to the next section by using the next button . All completed sections are represented by a check mark . Proceed to step 23a.




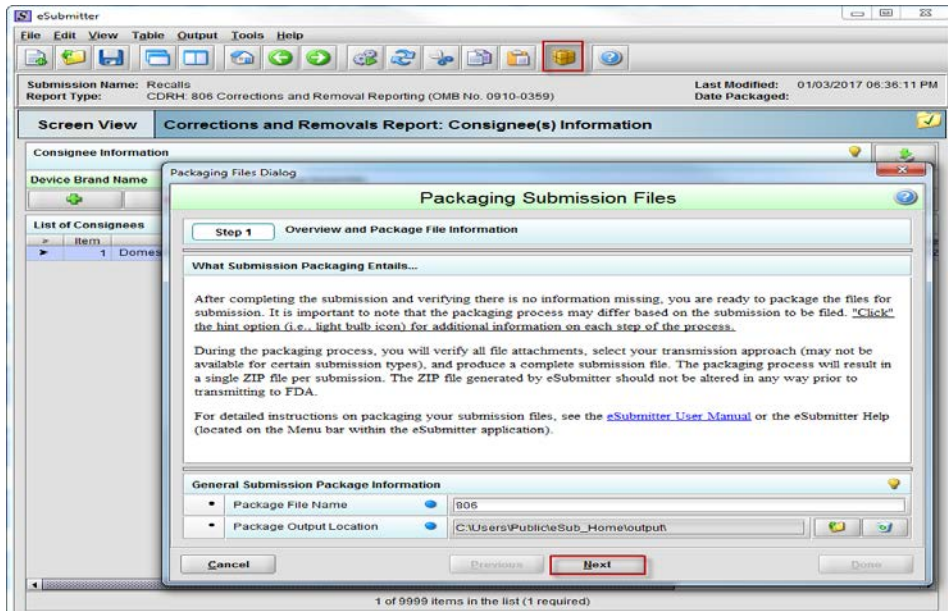
Step 23a: Click “Output” button to open drop down menu, select “Submission Report”. A Report Output Dialog box will appear. Ensure “System Default Viewer” is selected. Click “OK”. Proceed to step 23b.



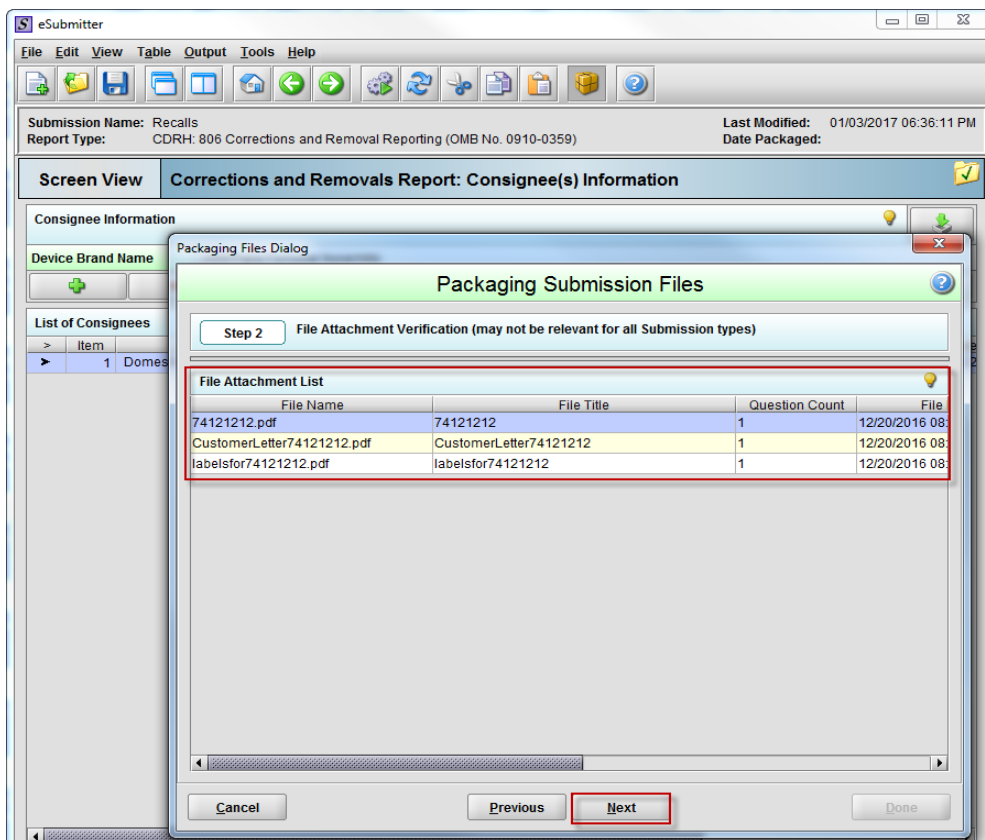
Step 23b: Review report for accuracy. If any information is incorrect, use the previous button  to go to the section/s and make the corrections. Proceed to step 24.



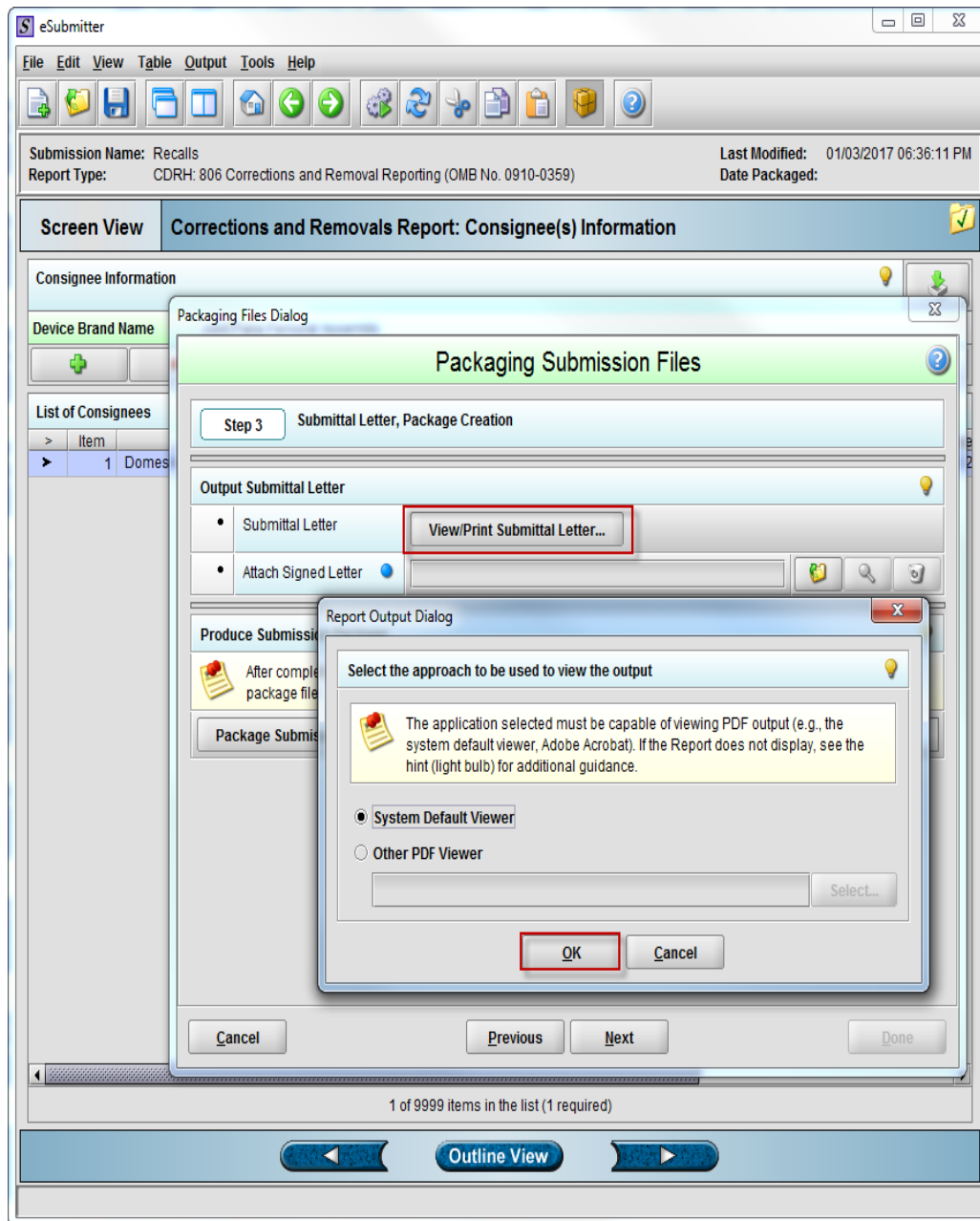
Step 24: Click on the “Package” button . A Packaging Files Dialog pop up box will appear. Read the Overview and Package File Information. Click “Next” and proceed to step 25.



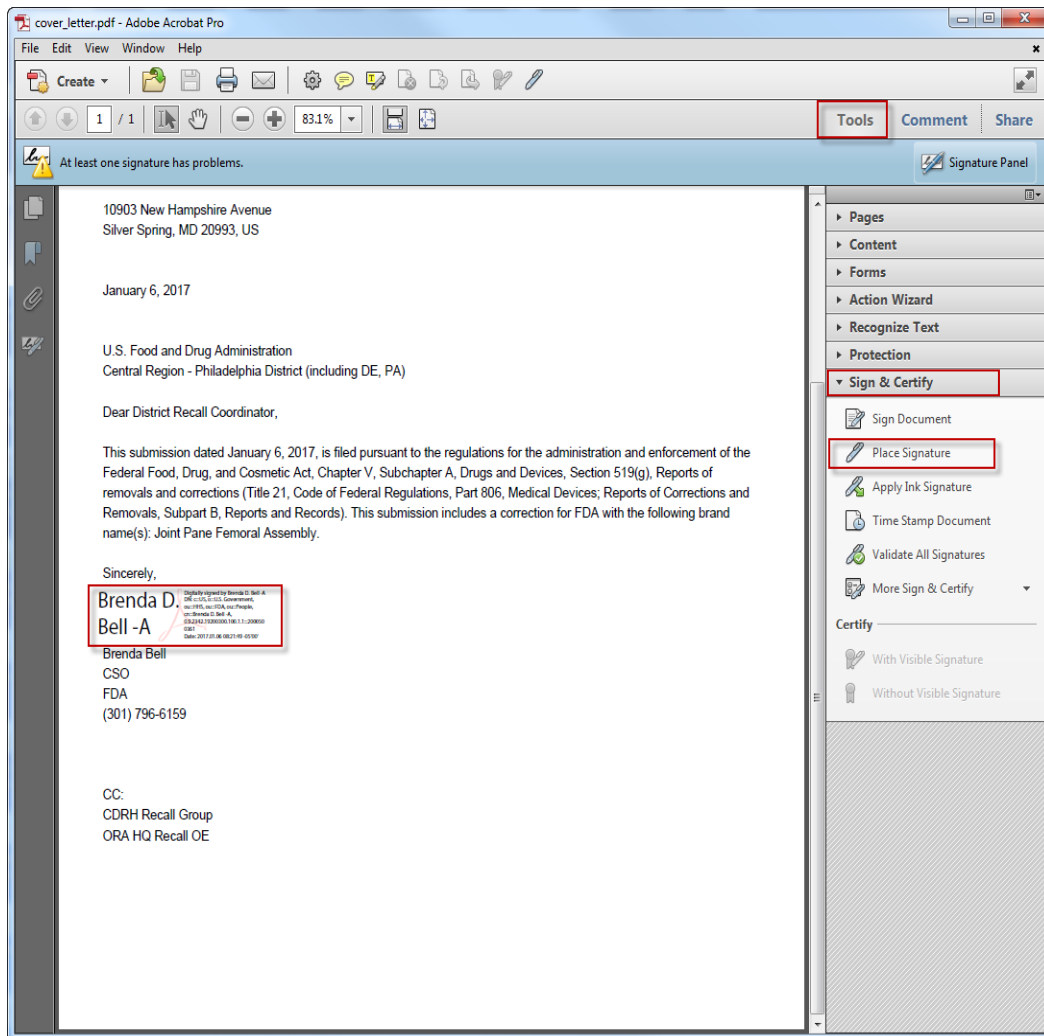
Step 25: Verify the file attachment(s) are correct. Click “Next” and proceed to step 26a.




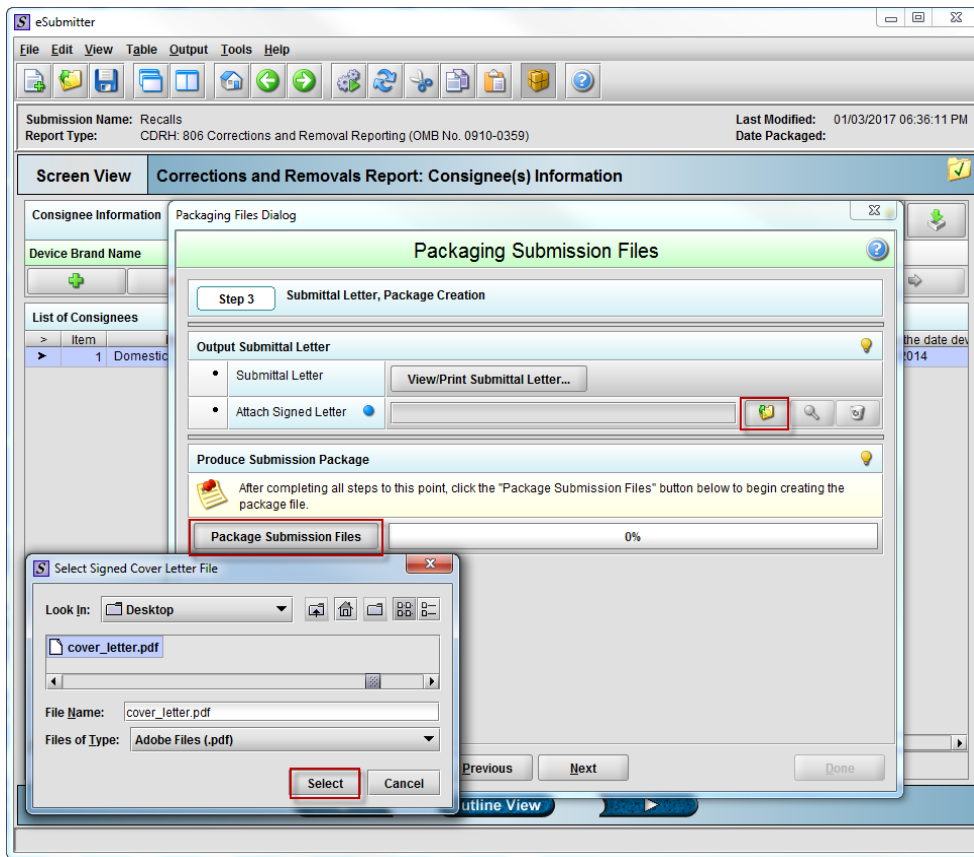
Step 26a: Create a signed letter. Click “View/Print Submitter Letter”. A Report Output Dialog pop up box will appear. Read the information and then click “OK”. Proceed to step 26b.



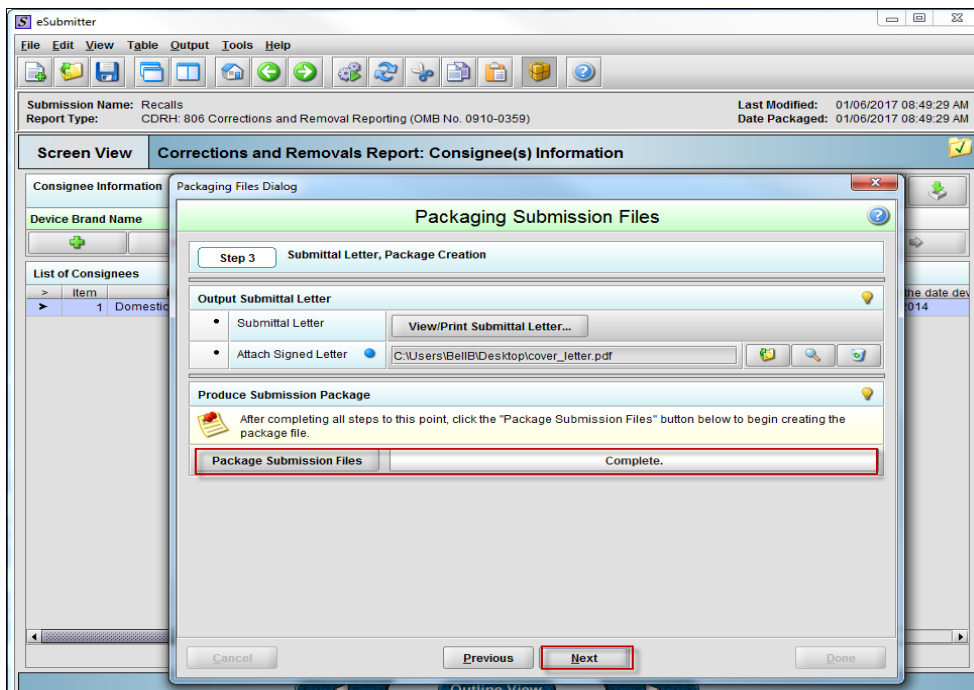
Step 26b: A copy of the letter appears. Click “Tools,” click “Sign & Certify,” click “Place Signature.” Use your cursor to add your signature. Click “OK” and save the letter on your desktop. Proceed to step 27.



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”.

