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FDA eSubmitter User Manual



Document Version 6.0

November 6, 2020

DOCUMENT HISTORY

Version Number	Date	Description
Version 1.0	May 26, 2004	OIVD Pre-Pilot Release (Software v1.00.00)
Version 1.1	August 27, 2004	Updated to reflect the enhancements incorporated in the Official OIVD Pilot Release (Software v1.00.01)
Version 2.0	March 15, 2005	Updated to reflect enhancements incorporated into the CeSub Pilot Release (software version 1.10). Updated for applicability to OIVD and Radiological Health.
Version 3.0	June 24, 2005	Updated for corrections and additional descriptions. Also updated to reflect the enhancements in Software versions 1.02.00 and 1.03.00.
Version 4.0	October 31, 2005	Updated to reflect the enhancements in software versions 1.04.00 through 1.07.00
Version 4.1	March 2, 2006	Revised the proxy server settings.
Version 4.2	August 7, 2007	Updated the instructions in the Packaging Submission Files section to incorporate the new packaging feature.
Version 4.3	January 7, 2008	Updated the instructions for release 1.28.01 to include link to special instructions for Windows Vista Users.
Version 4.4	May 2, 2008	Updated the uninstall instructions.
Version 4.5	March 16, 2009	Updated User Manual to accommodate eSubmitter as an FDA tool and not solely for the use of CDRH submissions.
Version 4.6	June 2, 2009	Updated to include revised links to the new eSubmitter website on FDA.gov > For Industry.
Version 4.7	November 15, 2009	Updated to include changes to eSubmitter per the Center for Tobacco Products needs.
Version 4.8	December 8, 2010	Updated to include information regarding CBER OBRR Pilot Evaluation Program for Blood Establishments That Collect Whole Blood and Blood Components.
Version 5.0	July 26, 2011	Updated for production release of CBER BLA/BLS submissions for Establishments that Collect Whole Blood and Blood Components, including Source Plasma
Version 5.1	February 5, 2012	Updated to include production release of CDER ICSR submission. Updated to include enhancements to the Packaging dialog, where very large submissions may be broken into smaller packaged zip files.
Version 5.2	June 5, 2012	Updated to include production release of CDRH Medical Device ISO 13485 submission, as well as the CDER SPL Establishment Registration & Product Listing submission.
Version 5.3	September 5, 2012	Updated to include information regarding CBER ICSR Adverse Event Reporting for Pilot Testing
Version 5.4	September 15, 2012	Updated to include information regarding CDRH eCopies submission type
Version 5.5	April 5, 2013	Updated to include production release of CTP Harmful and Potentially Harmful Constituents submission
Version 5.6	July 8, 2013	Updated to include production release of CBER OBRR Investigational New Drug (IND), including Antivenin
Version 5.7	May 6, 2015	Inactivated Investigational New Drug (IND), including Antivenin eCTD template
Version 5.8	August 29, 2017	Removed CVM References from FDA eSubmitter User Manual. Contact CVM about CVM eSubmitter.
Version 5.9	July 21, 2018	Removed all references to Windows Vista.
Version 6.0	November 6, 2020	Fixed page numbers, images, and broken links. Added MedDRA Section under Preferences. Enhanced Contact list.

Section 1: Introduction.....	1
Contents	1
Subsection 1.1: System Background.....	2
Subsection 1.2: About this Manual	3
Subsection 1.3: Software Installation	4
Section 2: Getting Started.....	7
Contents	7
Subsection 2.1: Starting the Software.....	8
Subsection 2.2: Setting User Preferences	14
Subsection 2.3: Creating a New Submission	26
Subsection 2.4: Copy an Existing Submission to Create a New Submission.....	30
Subsection 2.5: Re-open an Existing Submission.....	33
Section 3: Interface.....	34
Contents	34
Subsection 3.1: Application Window	35
Subsection 3.2: Toolbar	41
Subsection 3.3: Menu Bar - Output	43
Subsection 3.4: Menu Bar - Tools	44
Section 4: Preparing a Submission.....	51
Contents	51
Subsection 4.1: Entering Submission Information	52
Subsection 4.2.1: Question Types – Address and Contact Information	54
Subsection 4.2.2: Question Types – Option Lists.....	57
Subsection 4.2.3: Question Types – File Attachments	61
Subsection 4.2.4: Question Types – Guidance Documents	67
Subsection 4.2.5: Question Types – Text Fields and Messages	70
Subsection 4.2.6: Question Types – Product Codes	72
Subsection 4.2.7: Question Types – Standards.....	78
Subsection 4.2.8: Question Types – Sections as Tables	80
Subsection 4.3: Relationship Across Screens	81
Subsection 4.4: Saving Submission Entries or Changes.....	86
Subsection 4.5: Completing a Submission.....	87
Subsection 4.6: Completing a Submission (Packaging Submission Files).....	92
Section 5: FDA Recommended PDF File Specifications	105
Section 6: User Support.....	111

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Section 1: Introduction

Contents

This section contains the following topics:

Topic	See Page
System Background	2
About this Manual	3
Software Installation	4

Subsection 1.1: System Background

Introduction

The Food and Drug Administration (FDA) eSubmitter tool is a program that allows participants to electronically complete and submit information for various products to participating Centers. This tool is intended to automate the current paper submission process, allowing for quicker completion once users are accustomed to the software, as well as speed up the filing process with FDA. The eSubmitter software requires completing a series of questions in electronic forms and allows attaching documents, images and media files when additional information is needed.

If using the eSubmitter software is not desirable, you may continue to complete hard copies of reports and applications, though for the reasons stated above, electronic submission is strongly encouraged.

Subsection 1.2: About this Manual

Introduction

The instructions in this manual provide detailed information for installing the eSubmitter software into a computer with a **Microsoft Windows operating system**. In addition, this user guide assumes familiarity with terms associated with using a computer (**e.g. clicking and double-clicking**).

This manual is organized into five sections (including this one):

- **Section 1** provides an introduction and explains the requirements for running eSubmitter software, uninstall instructions, installation instructions, and proxy server instructions.
- **Section 2** provides instructions for starting the software, setting user preferences, and creating or reopening a submission.
- **Section 3** provides descriptive information about the eSubmitter software's interface and toolbar.
- **Section 4** provides instructions for preparing a submission for completion, which includes entering information, saving submission entries or changes, and packaging submission files.
- **Section 5** FDA Recommended PDF File Specifications.
- **Section 6** FDA User Support.

Please note that the screens used in this document are **examples** of what you might see while using the software. However, they may not appear exactly as shown.

Note: The terms submission, report, and submission report are used interchangeably in this guide to refer to a submission report.

Subsection 1.3: Software Installation

System Requirements

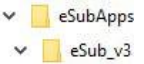
- Windows Operating System
- Adobe Acrobat Reader v5.0 or greater.
- 30 MB of disk space
- Access to a Compact Disk-Recordable drive (CD-R Drive)
- Software capable of viewing Rich Text, such as a Web browser, Microsoft Word, or Adobe Acrobat (full install version, not the Reader)

Uninstall Instructions

Before installing eSubmitter, **uninstall any other version of the software.**

Note: If you have a previous version of eSubmitter, be sure to save your data files and output files before uninstalling. If you do not have a previous version of eSubmitter, proceed to installing the current version of eSubmitter software.

To uninstall a previous version of eSubmitter, follow the instructions below.

Action	Graphic
<p>1. Use Windows Explorer to navigate to the location of the eSub (versions may add suffix) file folder on the workstation.</p>	
<p>2. Delete the eSubApps file folder by right-clicking and selecting Delete.</p>	
<p>3. When the previous version has been uninstalled, you are ready to install the current version of the eSubmitter software. See the following procedure.</p>	

Installation Instructions

The eSubmitter software can be loaded from the internet or from a CD-ROM. The following two subsections will discuss instructions for each.

Installation Instructions from Web Page

The eSubmitter software is available for downloading from the web at [FDA eSubmitter](#). To install the latest version of the eSubmitter software from this web page, follow the instructions below.

Subsection 1.3: Software Installation

Action	Graphic
1. Click the link for downloading the eSubmitter Software and save the jinstall.zip file to your computer.	
Download eSubmitter Software (64-bit compatible only)	
2. Unzip the jinstall.exe file and double-click on the file to run the eSubmitter installation.	
3. Follow the instructions provided. Following the instructions, the software will be installed locally on your hard drive in C:\eSubApps\eSub .	
Notes: 1. You can change the location where the software is installed by changing the file path on the Installation Directory dialog box when it appears.	
2. The software may be installed on a network. eSubmitter has a file locking option that you set to prevent users from accidentally overwriting the work of another. For details, see <i>Networking</i> on page 18.	

Subsection 1.3: Software Installation

Proxy Server Instructions

If you are using a proxy server to connect to the Internet, then you will need to change the application's properties file (**eSubmitter.properties**) to reference the server. See your System Administrator for help in changing the properties file.

The properties file is located in the application's JExpress subdirectory (**Program Files\Sub\JExpress**). Add the following switches **before** the -cp switch: -DproxySet=true -DproxyHost=[proxy_host] -DproxyPort=[proxy_port] (replace [proxy_host] and [proxy_port] with the appropriate information for your configuration).

If the proxy server requires a user id and password, add the following two properties to the **update.control** file that is also located in the **JExpress** subdirectory:

proxyUserName=
proxyPassword=

Section 2: Getting Started

Contents

This section contains the following topics:

Topic	See Page
Starting the Software	8
Setting User Preferences	14
Creating a New Submission	26
Copy an Existing Submission to Create a New Submission	30
Re-open an Existing Submission	33

Subsection 2.1: Starting the Software

Introduction

After you have successfully installed the eSubmitter software, you are ready to start up the application and create a new report.

Starting the Software

To start up the eSubmitter application, follow the instructions below.

Action

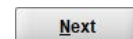
Graphic

1. **Start**, and select **Programs > FDA Submission Software > eSubmitter**.
2. You will see a Registration Dialog box, as shown below.

Registration Dialog Box



3. Click **Next** to continue the registration process. Or, click **Register Later** to register at another time. If you click **Next**, you will see a Registration Dialog box asking you to enter your contact information.



Subsection 2.1: Starting the Software

Registration Dialog Box: Contact Information

The screenshot shows a dialog box titled "Registration Dialog" with a sub-header "eSubmitter Registration". The main heading is "Step 1 Enter Contact Information". Below this is a "Contact" section with the following fields, each with a blue dot indicating it is required: Title (e.g., Mr., Ms.), First/Given Name, Middle Name, Last Name, Suffix (e.g., Sr, Jr, III), Degree(s) (e.g., PhD, JD), Occupation Title, and Email Address. At the bottom of the dialog are four buttons: "Register Later", "Previous", "Next", and "Done".

4. On the Registrati on Dialog box, enter the information requested. Required entries are indicated by blue dots. Click **Next**. You see a Registrati on Dialog box asking you to enter address information.

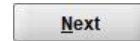
Next

Registration Dialog Box: Address Information

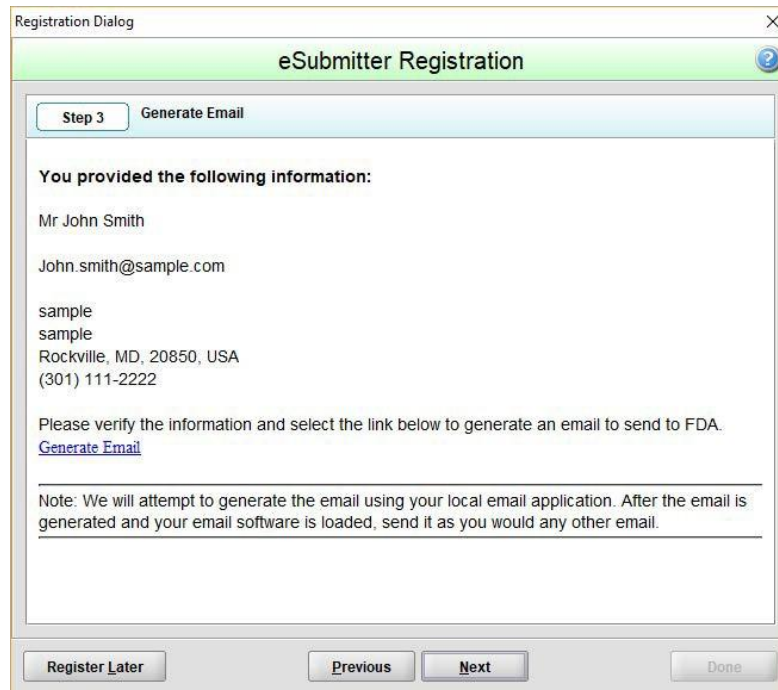
The screenshot shows the same dialog box, now at "Step 2 Enter Address Information". The "Address" section includes the following fields, all with blue dots: Establishment Name, Country (with radio buttons for "United States of America" and "Other (select below)"), Address - Line 1, Address - Line 2, City, State, Province, or Territory, and Post Office or Zip Code. Below this is a "Phone Numbers" section with a "Telephone number" field, also with a blue dot. The "Next" button is now active.

Subsection 2.1: Starting the Software

5. On the **Address Information** dialog box, enter the information requested. Click **Next**. You see a *Registration Dialog* box to generate an email.

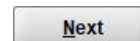


Registration Dialog Box: Generate Email

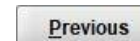


The image shows a screenshot of a software dialog box titled "Registration Dialog" with a sub-header "eSubmitter Registration". The dialog is in "Step 3: Generate Email". It displays a summary of the user's information: "Mr John Smith", "John.smith@sample.com", "sample", "sample", "Rockville, MD, 20850, USA", and "(301) 111-2222". Below the summary, it asks the user to verify the information and click a "Generate Email" link. A note at the bottom states: "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." At the bottom of the dialog, there are four buttons: "Register Later", "Previous", "Next", and "Done".

6. In the Generate Email step, you see a summary of the information you entered. If the information is correct, click **Next**. If the information is not correct, click **Previous** until you return to the screen that you need to correct.



/



7. Click **Generate Email** in the dialog box. You will see an email.
8. Click **Send** in the email. You see a Registration Dialog box to check results.

Subsection 2.1: Starting the Software

Registration Dialog Box: Check Results

The screenshot shows a window titled "Registration Dialog" with a sub-header "eSubmitter Registration". The main content area is titled "Step 4 Check Results". It contains the following text and options:

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

At the bottom of the dialog box, there are four buttons: "Register Later", "Previous", "Next", and "Done".

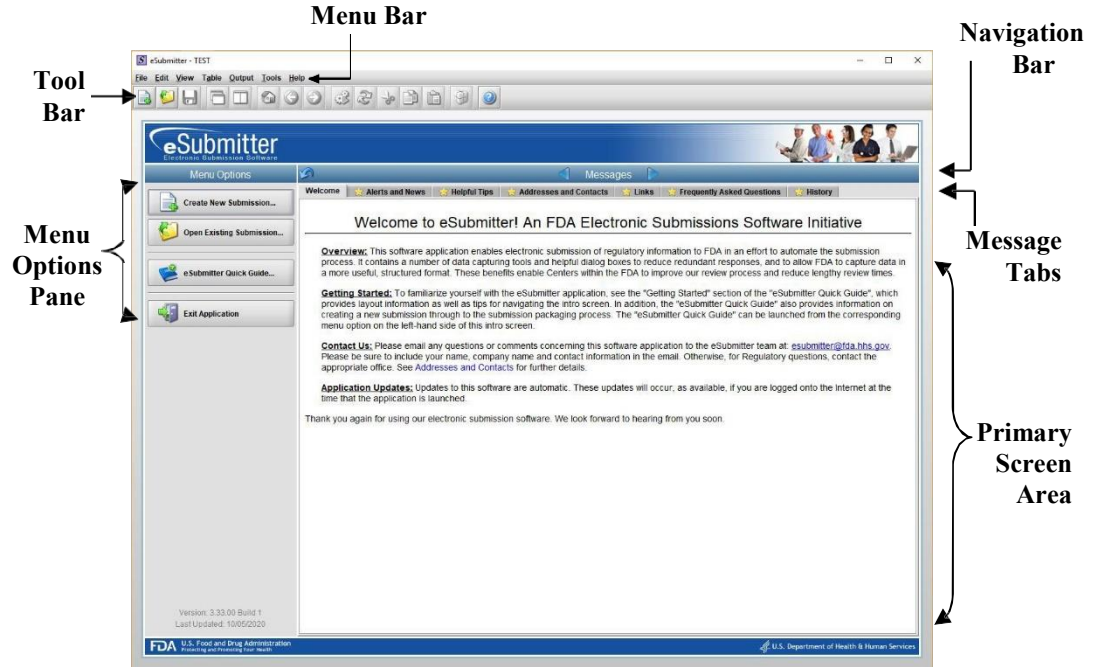
9. Select the button corresponding to either **Yes the Email was sent correctly** or **No there was a problem**.
 10. Click **Done** if the email was successful and to complete the registration process.
 11. Next, you will see the *Intro Screen*, which is described in the subsequent section.
-





A rectangular button with the text "Done" centered inside.

Subsection 2.1: Starting the Software








Intro Screen

The Intro Screen provides an introduction to the software and will serve as your home screen. The Intro Screen will be displayed as shown below and the contents and tools available in the Intro Screen are described in the following table.



Function	Icon	Description
Create New Submission		Allows you to create a new submission entry. The New Submission Dialog box will appear. See section Creating a New Submission for more detailed information.
Open an Existing Submission		Allows you to open an existing submission. The Open Existing Submission Dialog box will appear. See section Subsection 2.5: Re-open an Existing Submission for more detailed information.
eSubmitter Quick Guide		Launches the eSubmitter Quick Guide. If the Quick Guide does not contain the information you are searching for, see the full length eSubmitter User Manual .
Exit Application		Closes the eSubmitter application.

Subsection 2.1: Starting the Software

Help Topics		Launches the eSubmitter User Manual .
Forward Navigation Arrow		This arrow allows you to move forward through the Message Tabs .
Backward Navigation Arrow		This arrow allows you to move backwards through the Message Tabs .
Collapse/Expand Arrows		Allows you to collapse and expand the Menu Options portion of the Intro Screen.
Notification Stars		The yellow stars are intended to notify users when new messages are available. The star appears next to the message tab header with new unread messages.
Category Filter		Allows you to filter the message information to display only generic information or those messages pertaining to a particular program. eSubmitter will remember the selected filter option upon closing and reopening the application.
Mark as Read		This checkbox enables you to indicate which message tabs have been read. Mark this checkbox to remove the yellow star shown next to the tab header. Unmark this checkbox to make the yellow star on the applicable tab header reappear.

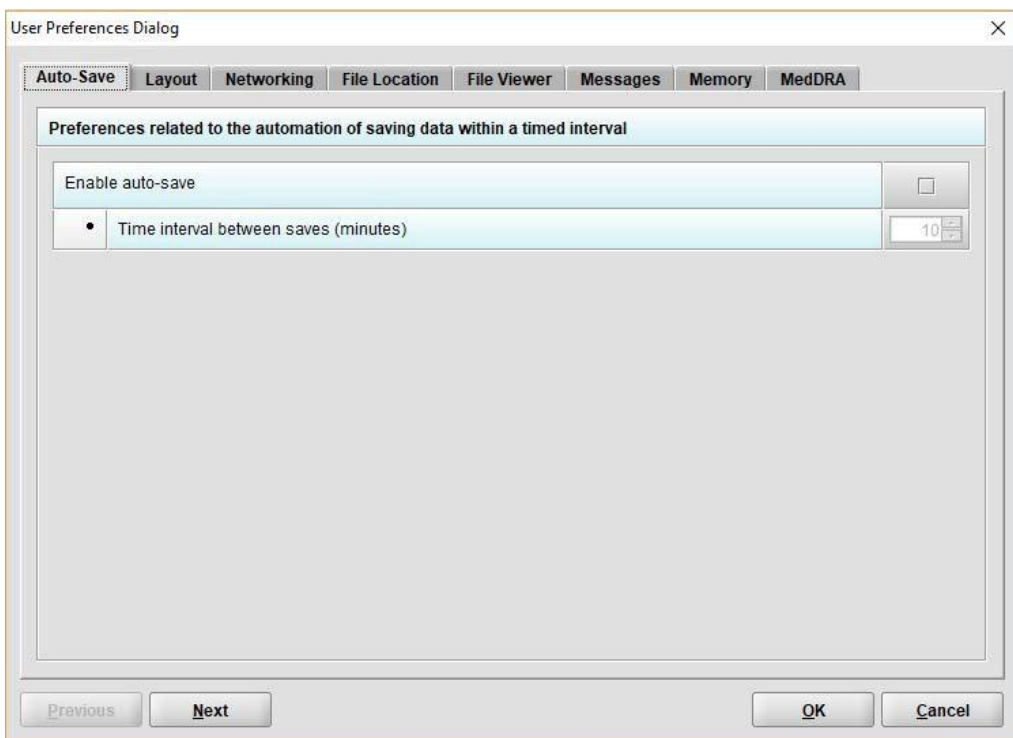
Subsection 2.2: Setting User Preferences

Introduction

eSubmitter allows you to set preferences for the following categories:

- Auto Save
- Layout
- Networking
- File Location
- File Viewer
- Messages
- Memory
- MedDRA

Setting preferences prior to creating a submission will make the process much easier. To begin setting preferences, click on the **File Menu > Preferences**. The User Preferences Dialog box will appear (as shown below).




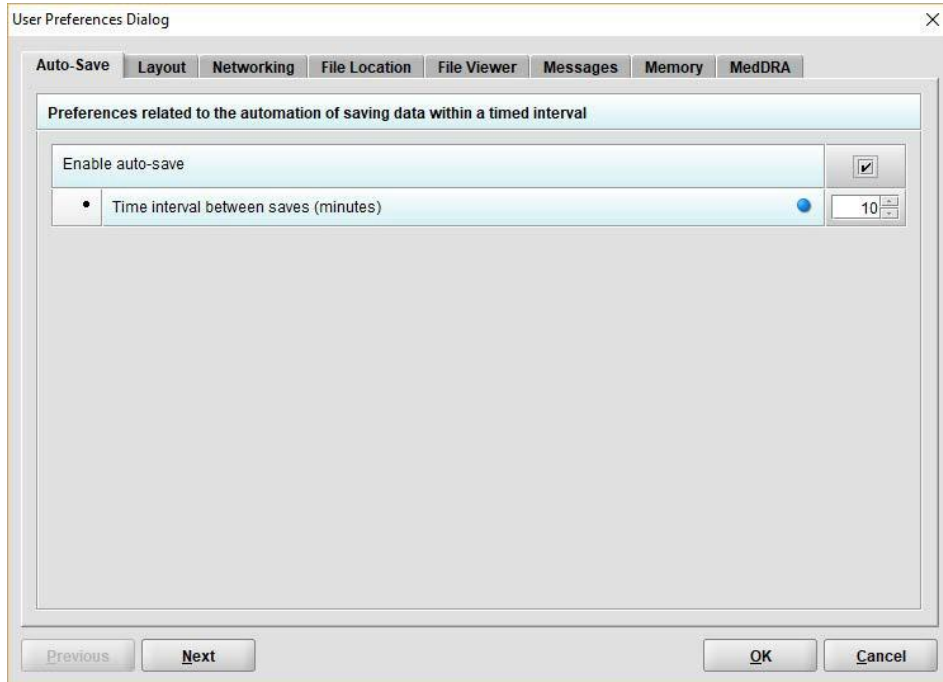
The subsections below will explain how to set preferences for each category.

Subsection 2.2: Setting User Preferences


Auto Save

Allows you to automatically save your report while you work. You can also set the interval for how often you want to save your report. At default, auto-save is automatically enabled and set to save files at 10-minute intervals.

Note: The **Blue Dot**  indicates that a response to the question is required.

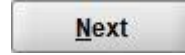


To change the auto-save option:

Action	Graphic
1. Check the box to enable the auto-save feature (i.e., to turn auto save on) or clear the checkbox to disabled the auto-save feature (i.e., to turn auto-save off).	
2. If you cleared the checkbox, go to step 3. If you selected the checkbox, in the time interval box: Enter the interval (in minutes) for how often you want to save the file. OR Use the up and down arrows to select the interval.	

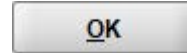
Subsection 2.2: Setting User Preferences

3. If you want to change or set the layout, click **Next** or the **Layout** tab. See the description for **Layout** below.



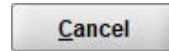
OR

If you are finished and satisfied with your changes, click **OK** to close the User Preferences Dialog box with your changes saved.



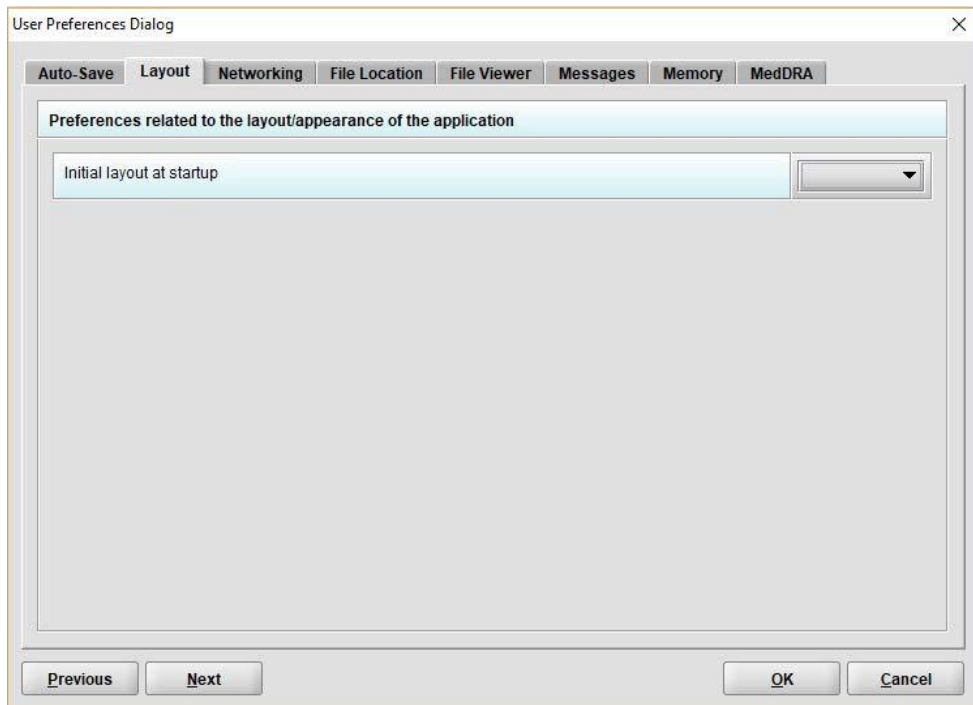
OR

Click **Cancel** to close the User Preferences Dialog box without saving any changes.



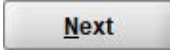
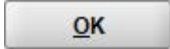
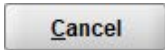
Layout

Allows you to set whether you want eSubmitter to open reports in the simple or expert layout when you start up the application. At default, eSubmitter opens reports in the simple layout. For more information, see descriptions in the Application Window section on page 35.



To change the layout when eSubmitter starts up, follow the instructions below.

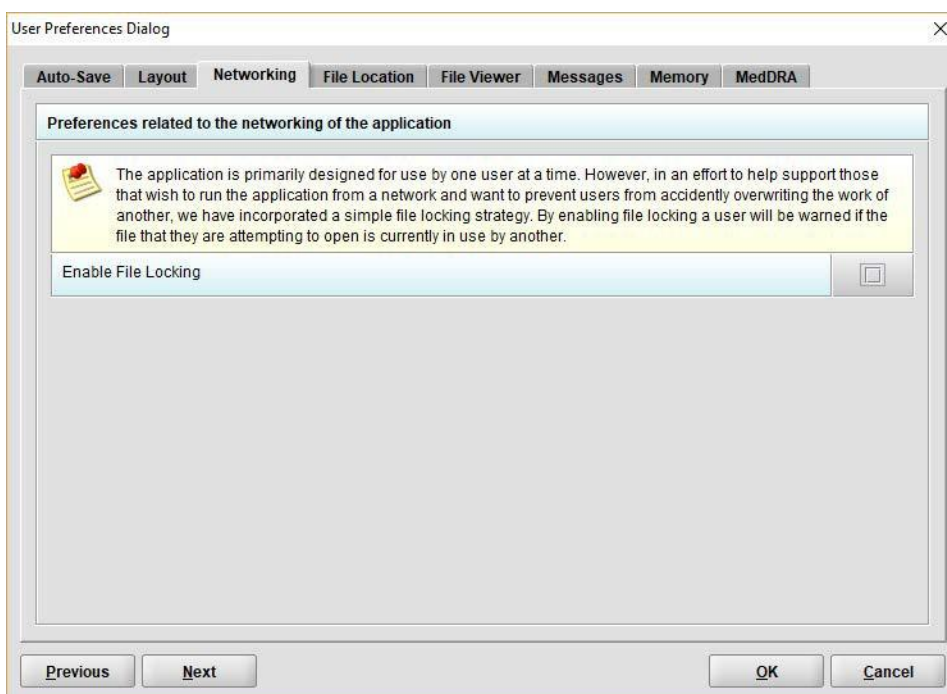
Subsection 2.2: Setting User Preferences

Action	Graphic
1. In the initial layout box, select Simple or Expert from the drop-down menu. For more information on these layout options, see Subsection 3.1: Application Window, beginning on page 35.	
2. If you want to change the settings for networking, click Next or the Networking tab. See the description for Networking below.	
OR	
If you are finished and satisfied with your changes, click OK to close the User Preferences Dialog box with your changes saved.	
OR	
Click Cancel to close the User Preferences Dialog box without saving any changes.	

Subsection 2.2: Setting User Preferences

Networking



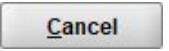
Allows you to set file locking when using the software on a network. The application is primarily designed for use by one user at a time. However, in an effort to help support those that wish to run the application from a network, and to prevent users from accidentally over-writing the work of another, a simple file locking strategy has been incorporated. By enabling file locking, a user will be warned if the file that they are attempting to open is currently in use by another user. At default, eSubmitter opens without file locking.



To enable file locking, follow the instructions below.

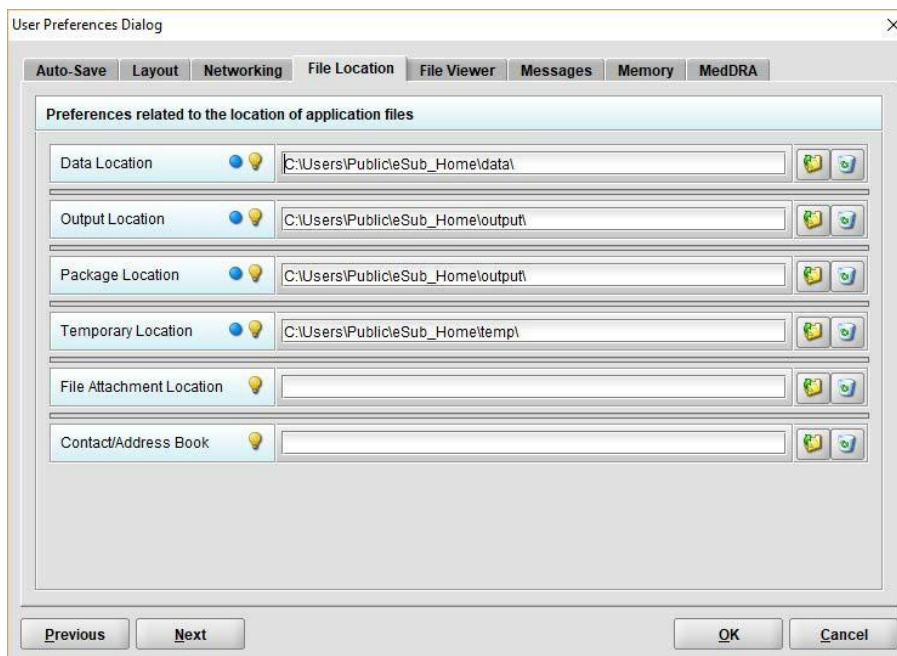
Action	Graphic
1. Click to select the Enable File Locking checkbox (to turn file locking on) or clear the checkbox (to turn file locking off).	<input checked="" type="checkbox"/>

Subsection 2.2: Setting User Preferences

Action	Graphic
2. If you want to change the settings for networking, click Next or the File Location tab. See the description for File Location below.	
OR	
If you are finished and satisfied with your changes, click OK to close the User Preferences Dialog box with your changes saved.	
OR	
Click Cancel to close the User Preferences Dialog box without saving any changes.	

File Location

Allows you to change the location where your report data files are stored when saved and the location where files are generated when output (e.g., reports and packaged submissions). For more information on packaging files for submission, go to Package Files for Submission on page 92.



To change the file location for each of the folders:

Subsection 2.2: Setting User Preferences

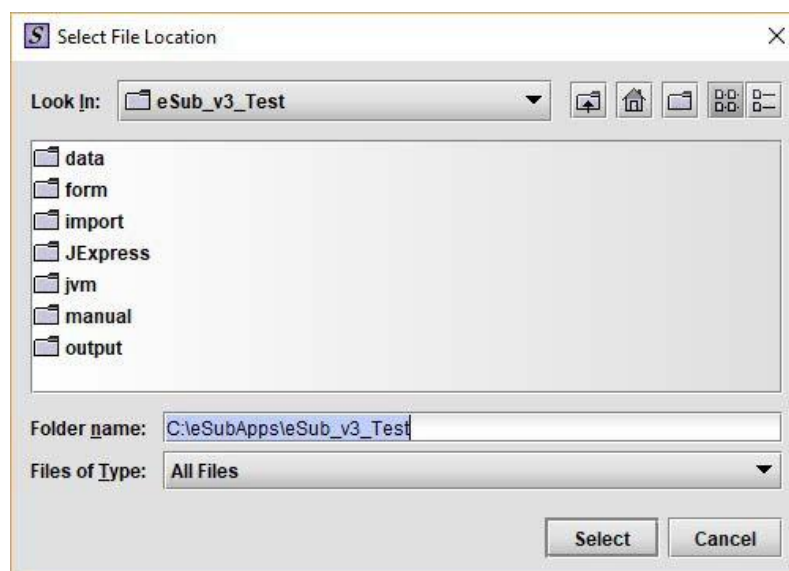
Action

Graphic

1. Click the **Select Location** icon right of the text box.
2. The Select File Location dialog box will appear. Click the **Look In** box, and navigate to the file folder where you would like your files stored.



Select File Location Box



3. Once you have navigated to the location, highlight the specific folder and click **Select** in the bottom right-hand corner of the dialog box. Your files will now be stored in the new specified location.

Select

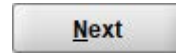
Recommended Location:

If installed on a Network drive (on Windows XP or earlier): The location of your data and output files will be contained within the **eSub** directory where the application was installed.

If installed on a Workstation (on Windows XP or earlier): data and output files should be hosted in the following location: **C:\Documents and Settings \eSub_Home**.

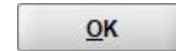
Subsection 2.2: Setting User Preferences

4. If you want to change the settings for networking, click **Next** or the **File Viewer** tab. See the description for **File Viewer** below.



OR

If you are finished and satisfied with your changes, click **OK** to close the User Preferences Dialog box with your changes saved.



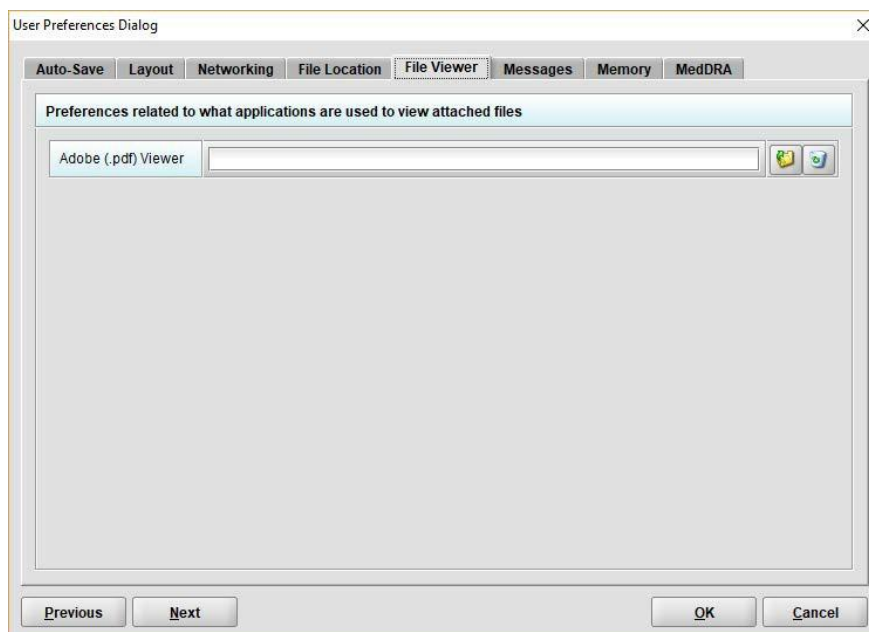
OR

Click **Cancel** to close the User Preferences Dialog box without saving any changes.



File Viewer

Allows you to identify the application that you will use as your PDF viewer. (Generally, Adobe Acrobat is used as the application for viewing PDFs.)



Follow these instructions to set up your PDF viewer:

Action

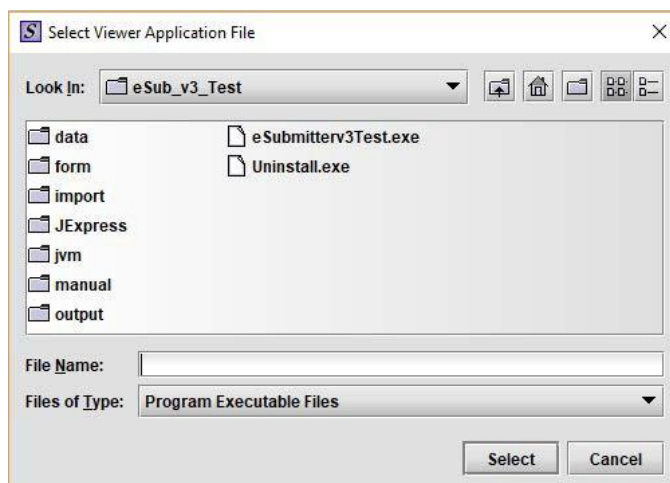
Graphic

1. Click the **Select Location** icon to the right of the text box. The Select Viewer Application File box is displayed (as shown below).



Subsection 2.2: Setting User Preferences

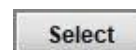
Select Viewer Application File Box



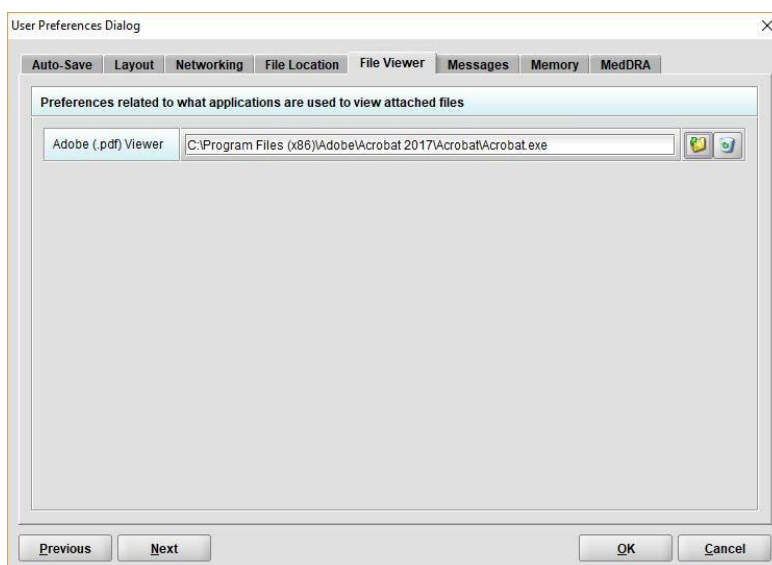
2. Click in the **Look In** box, and navigate to the file folder for Adobe Acrobat or the Acrobat Reader. The location is usually either:

- **Program Files > Adobe > Acrobat > Acrobat.exe**
- **Program Files > Adobe > Reader > AcroRd32.exe**

3. Highlight (select) **Acrobat.exe** or **AcroRd.exe** and click **Select**. The **File Viewer** tab in the User Preferences Dialog box will appear in the text box as shown below.



User Preferences Dialog Box



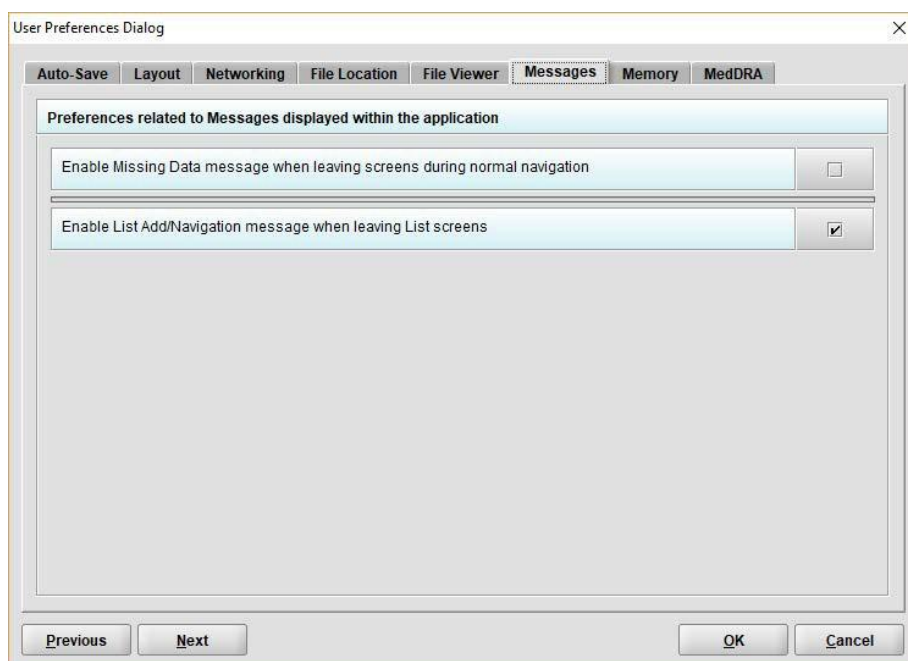
4. Click **OK**.








Subsection 2.2: Setting User Preferences

Messages

Allows you to indicate whether you will receive missing data messages upon leaving a data entry screen. Allows you to indicate whether you will receive List Add/Navigation messages when leaving list screens.



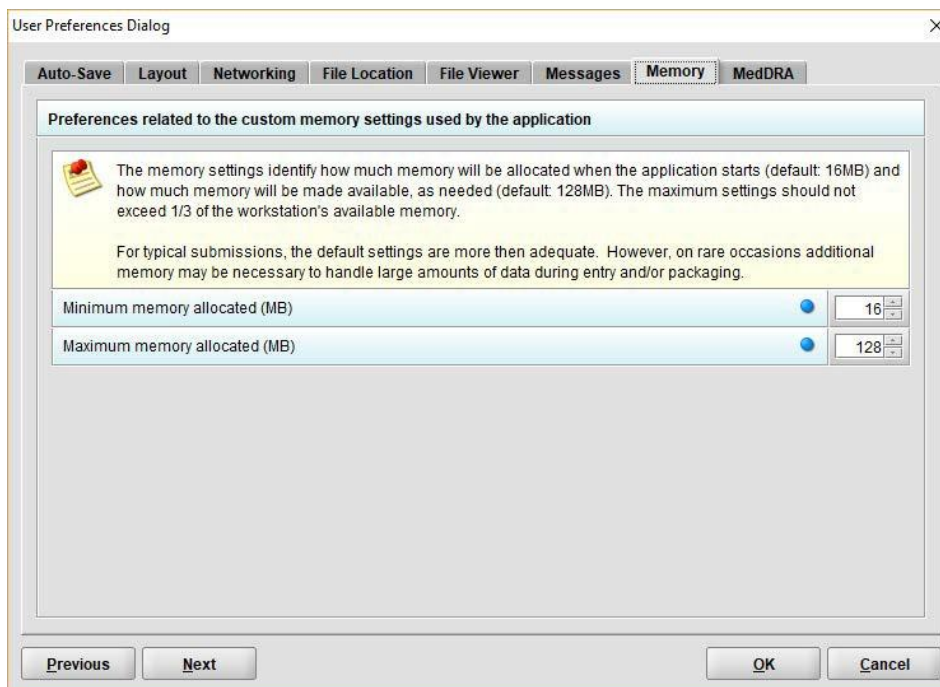
To enable these functions, do the following:

Action	Graphic
1. Check the box on the right to enable Missing data messages	
2. To disable this function, check the box so that it is clear of any check marks.	
3. Check the box on the right to enable List Add/Navigation messages	
4. To disable this function, check the box so that it is clear of any check marks.	
5. Click OK .	

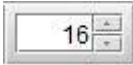
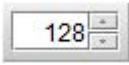

Subsection 2.2: Setting User Preferences

Memory

Allows you to identify how much memory will be allocated when the application starts (default: 16MB) and how much memory will be made available, as needed (default: 128MB).



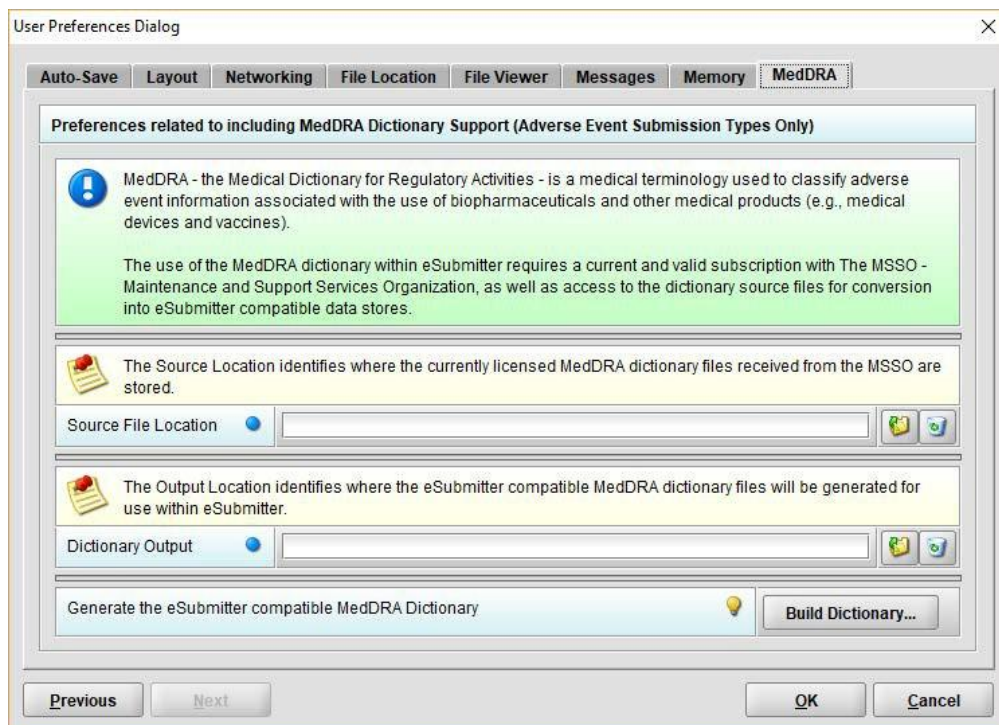
To enable this function, do the following:

Action	Graphic
1. To change the minimum memory allocated, use the arrows to the right to increase or decrease or by entering a number in the field.	
2. To change the maximum memory allocated, use the arrows to the right to increase or decrease or by entering a number in the field.	
3. Click OK .	

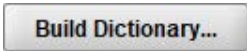
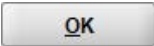
Subsection 2.2: Setting User Preferences

MedDRA

Allows you to create a MedDRA of adverse event information.



To enable this function, do the following:

Action	Graphic
1. Select a Source File location	
2. Select a Dictionary Output location	
3. Select Build Dictionary. Application will create the dictionary based on the source data	
4. Click OK .	

Subsection 2.3: Creating a New Submission

Introduction

This section provides an overview of creating a new submission report.

Note: Before proceeding, make sure you have already reviewed the **Introduction**, **Getting Started**, and **Interface** sections of this user manual. These sections provide valuable information that is necessary in order to follow and understand the instructions in this section.

There are two methods for creating a new submission report: starting from scratch with a completely blank report or copying an existing report and making the required changes. The purpose for copying an existing report would be to save time assuming many of the responses are the same. This might be the case if you have an existing report from the same product line or you are submitting a supplement. The steps involved for both are provided below.

Follow the steps below to create a new blank submission from scratch:

Create a New Submission

Action

Graphic

1. The eSubmitter application should be open on your computer desktop. If it is open, and you see the Intro Screen, go to step 2. (If it is not open, open the application first by following the instructions in Starting the Software on page 8.)
-

Subsection 2.3: Creating a New Submission

Action

Graphic

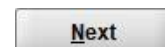
2. Click the **Create New Submission** button from the **Menu Options**. Or you may select **File > New** or, click the **New Report** icon on the Tool Bar. The New Submission Dialog box is displayed (as shown below).

A screenshot of the "New Submission Dialog" window. The title bar says "New Submission Dialog". The main title is "Create New Submission". Below the title is a tab labeled "Step 1 Select Submission Type". A table titled "List of Available Submission Types" is displayed. The table has columns for Name, Version, and Version Dat. The first row is selected and highlighted in blue. Below the table is a section titled "Description of Selected Submission Type" which contains text about the CBER eSubmitter Program. At the bottom are buttons for "Cancel", "Previous", "Next", and "Create".

Name	Version	Version Dat
CBER: BLA for Whole Blood and Blood Components, including Source Plasma	1.0	01/28/2015 12:02:15
CBER: Electronic Reporting for Blood Collection Centers	1.0	07/06/2016 07:14:37
CBER: Electronic Vaccine Adverse Event Reporting (eVAERS)	2.15	10/01/2020 05:06:40
CDER/CBER: Generic Drug Facility Electronic Self-Identification	1.0	05/07/2015 03:48:24
CDRH: 806 Corrections and Removal Reporting (OMB No. 0910-0359)	1.1.3	12/16/2019 11:16:59
CDRH: Allegation Reporting (Medical Devices) (OMB No. 0910-NEW)	1.2	06/19/2014 10:14:16
CDRH: In Vitro Diagnostic Device - 510(k)	1.3	01/01/2015 11:00:27

- 3 **Step 1. Select a Submission Type.** The New Submission Dialog wizard is comprised of two parts. The first section (top portion of the window) requires that you select which **Submission Type** to create. When you click on the **Submission Type**, the bottom portion of the window displays information related to the corresponding submission type (as shown in the New Submission Dialog box figure above).

Once you have selected the appropriate **Submission Type**, click **Next**.

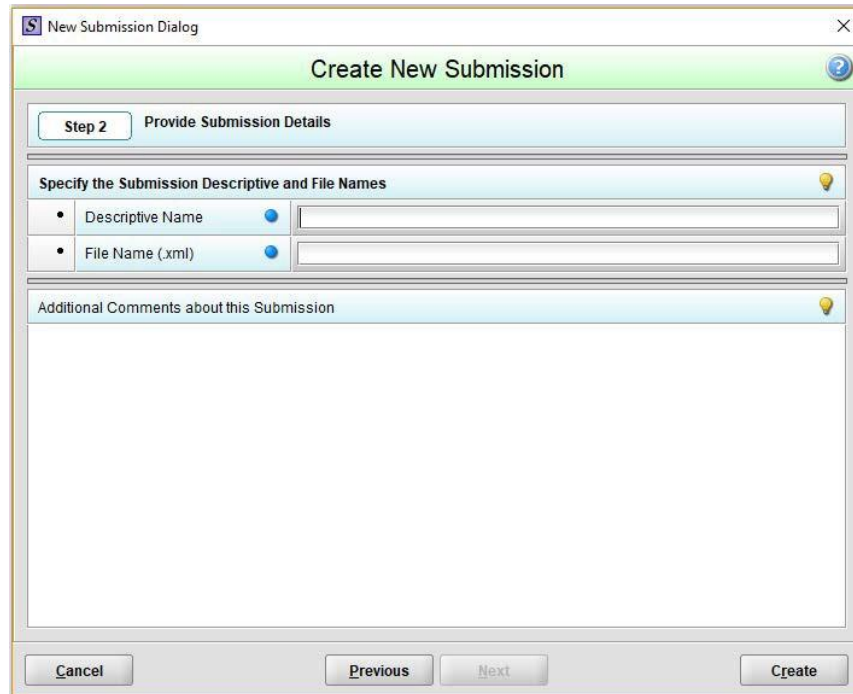


Subsection 2.3: Creating a New Submission

Action

Graphic

4. Step 2. Provide Submission Details (as shown below).

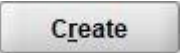


The screenshot shows a dialog box titled "New Submission Dialog" with a sub-header "Create New Submission". The dialog is in "Step 2: Provide Submission Details". It contains three main sections: "Specify the Submission Descriptive and File Names" with two required input fields for "Descriptive Name" and "File Name (.xml)", and "Additional Comments about this Submission" with a large text area. At the bottom are "Cancel", "Previous", "Next", and "Create" buttons.

Complete the fields on this dialog box as follows:

- **Descriptive Name** – Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (Required Entry, as indicated by the blue dot.)
- **File Name** – Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.) **File names should not contain more than 100 characters. Do not use symbols when naming the files.** For example, do **not** use slashes (/)\, tildes (~), asterisks (*), periods (.), brackets [], single quotation marks (‘), double quotation marks (“) or parentheses ().
- **Provide additional comments...** – Enter any additional information about this report (Optional Entry).

Subsection 2.3: Creating a New Submission

Action	Graphic
5. When you are finished entering all information in the fields, click Create . The first screen of your new blank submission report is displayed.	 A rectangular button with a light gray background and a thin black border. The word "Create" is centered on the button in a dark gray, sans-serif font.

Subsection 2.4: Copy an Existing Submission to Create a New Submission

Copy an Existing Submission to Create a New Submission

To copy an existing submission in order to create a new submission, follow the instructions below.

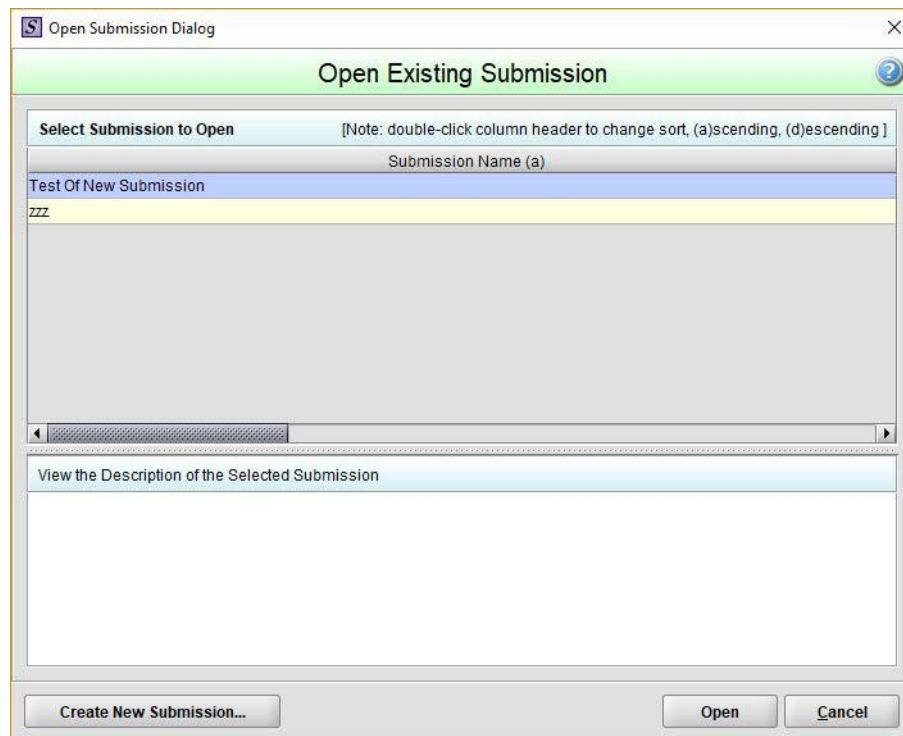
Action

Graphic

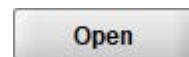
1. Click **File > Open**. (Or, click the **Open** icon on the Tool Bar.) The Open Submission Dialog box is displayed (as shown below).



Open Report Data Dialog Box



2. Click to select the existing submission report to be used as a template, and click **Open**. The submission report is displayed on your computer.
3. Click **File > Save As**. The Save Submission AsDialog box is displayed (as shown below).



Subsection 2.4: Copy an Existing Submission to Create a New Submission

Action

Graphic

Save
Submission As
Dialog Box

Save As Submission Dialog

Create New Submission From Loaded Submission

Specify the Submission Descriptive and File Names

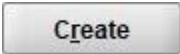
- Descriptive Name
- File Name (.xml)

Additional Comments about this Submission

Cancel Create

4. Complete the fields on this dialog box as follows:
 - **Descriptive Name** – Enter any descriptive name, as long as it is unique to the submission list. Use a name that distinctly identifies the report to you. (Required Entry, as indicated by the blue dot.)
 - **File Name** – Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.)
 - **Provide additional comments...** – Enter any additional information about this report (Optional Entry).

Subsection 2.4: Copy an Existing Submission to Create a New Submission

Action	Graphic
<hr/> <p>5. When you are finished entering all information in the fields, click Create.</p> <p>The first screen of your new submission report is displayed.</p> <hr/>	
<p>6. Since you copied an existing submission, it already has many or all questions answered. You now have the opportunity to go through and change responses for this new submission. (Creating a new submission in this manner is convenient if you are creating a supplemental report or creating a report for a product in an existing product family.)</p>	
<p>7. You are now ready to change the responses in this submission, go to Entering Submission Information on page 52.</p> <hr/>	

Subsection 2.5: Re-open an Existing Submission

Re-open an Existing Submission


To re-open an existing submission, follow the instructions below.

Action

Graphic

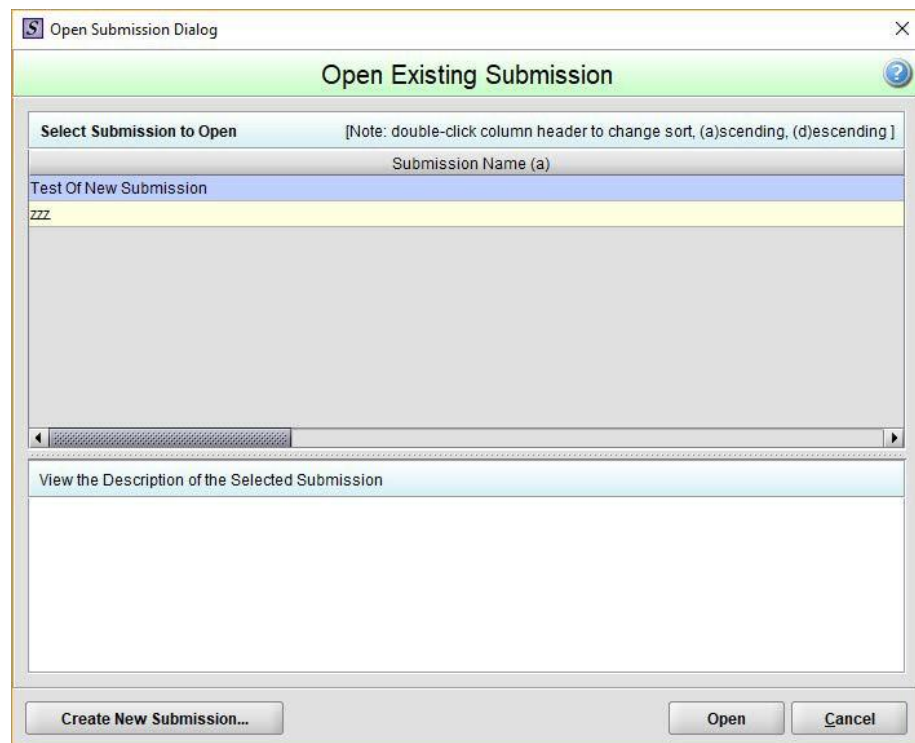
1. Click **File > Open** on the menu bar.

OR

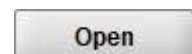
Click  on the tool bar.

The Open Existing Submission Dialog box is displayed (as shown below).

Open Existing Submission Dialog Box



2. Click to select (highlight) the submission that you wish to open, and click **Open**. The selected submission is displayed.



Section 3: Interface

Contents

This section contains the following topics:

Topic	See Page
Application Window	35
Toolbar	41
Menu Bar – Output	43
Menu Bar – Tools	44

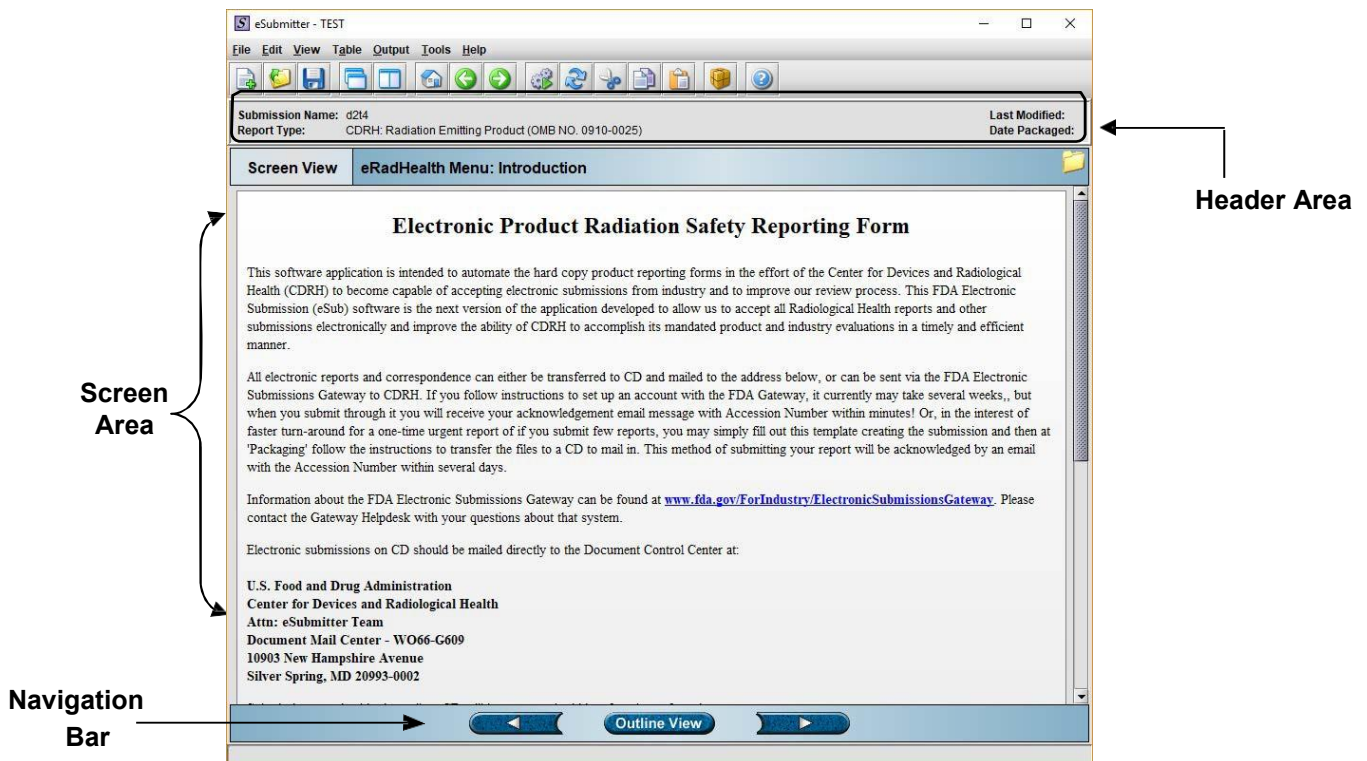
Subsection 3.1: Application Window

Introduction This section describes eSubmitter’s Application Window and its different parts.

The eSubmitter Application Window has two layouts that change the orientation of the text on the screen: **simple** and **expert**. When you first start up the application, eSubmitter opens in the simple layout with the screen view.

Simple View The **simple** view shows only the current data entry screen and “hides” the outline tree. The simple view separates the Submission Display Screen into three additional areas (as shown below):

- **Header Area** (located at the top)
- **Outline Area or Screen Area** (located in the middle)
- **Navigation Bar** (located at the bottom), which allows forward and backward movement through the screens, as well as the ability to switch back and forth between the outline or screen view.

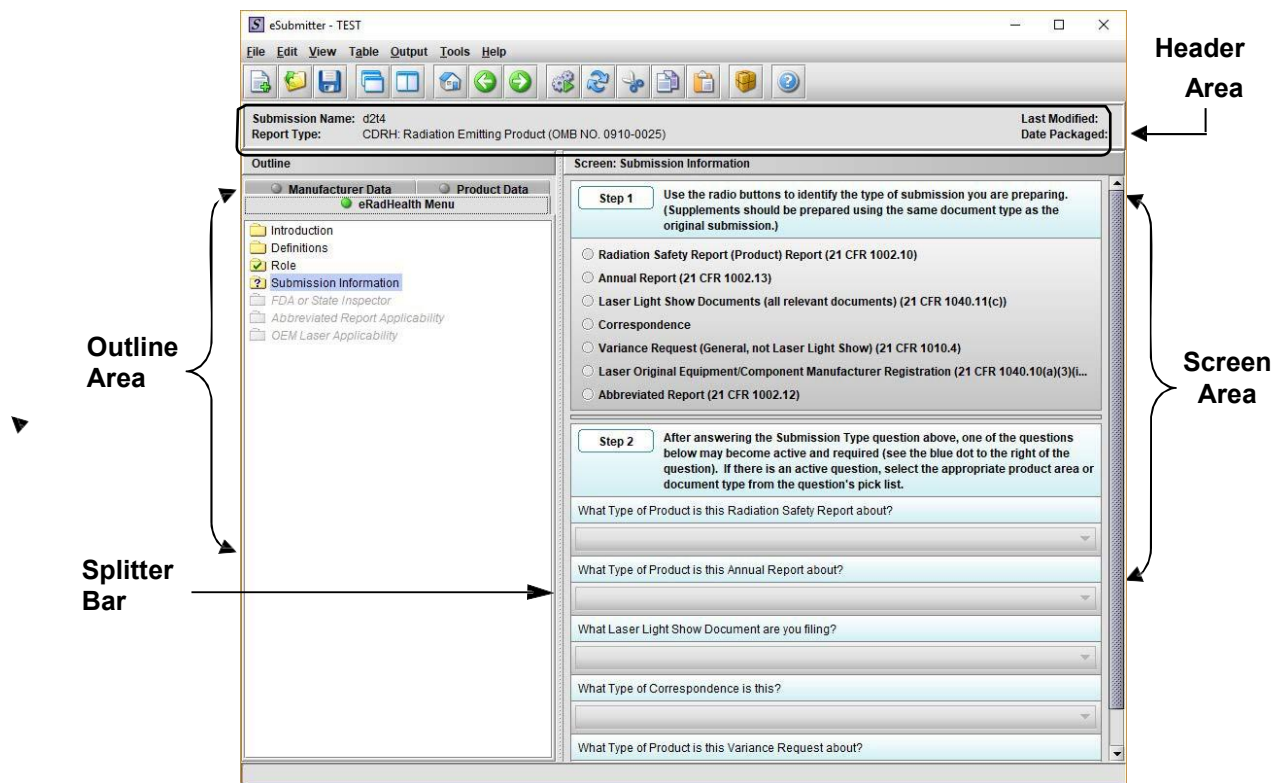


Subsection 3.1: Application Window

Expert View

The **expert** view allows the user to navigate through the form using an outline tree located on the left side of the screen. The expert view separates the Submission Display Screen into four additional areas (as shown below).

- **Header Area** (located at the top)
- **Outline Area** (located at the left)
- **Screen Area** (located to the right)
- **Splitter Bar** (located between the outline and screen areas)



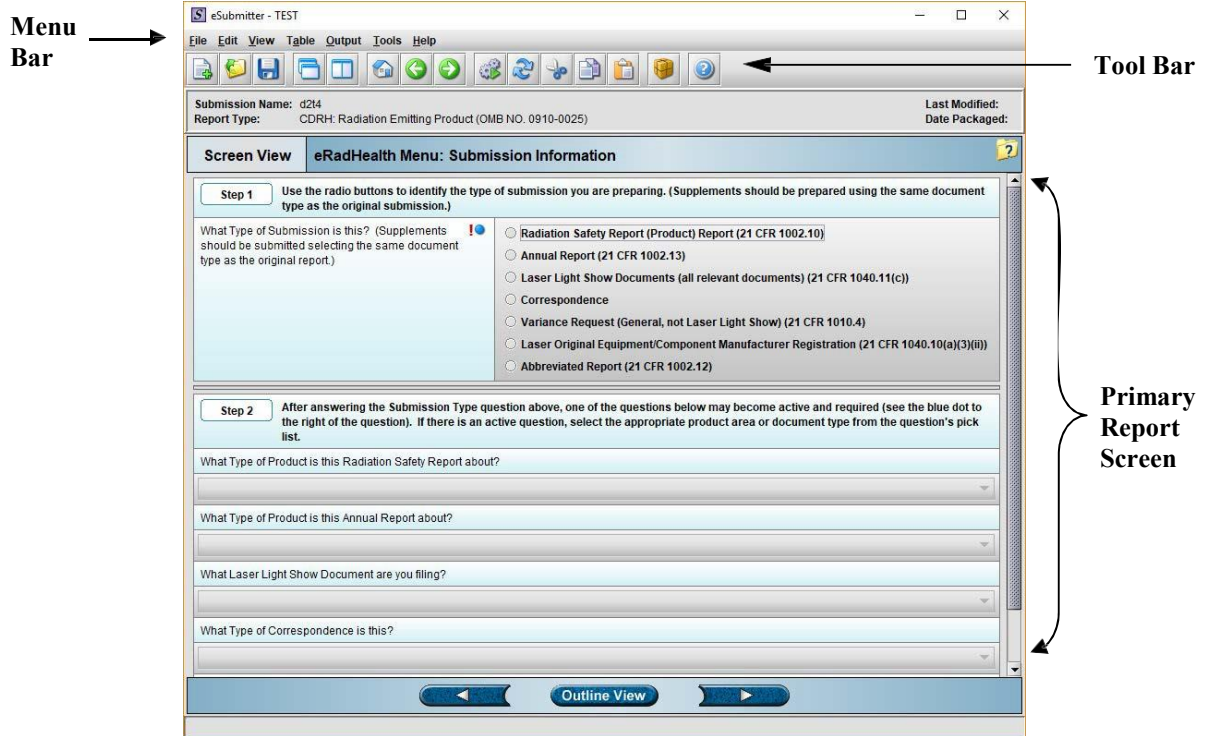
Subsection 3.1: Application Window

Layouts

Both layouts provide the same information. It is your choice as to which layout works best for you. You can switch between the two layouts very easily, as well as customize eSubmitter to open in the expert layout. To learn how to change eSubmitter so that the application opens in the expert layout, rather than in the simple layout, see User Preference Tab – Layout on page 16.

The Application Window, whether in simple or expert layout, is divided into three parts, as shown below.

1. Menu Bar
2. Tool Bar
3. Primary Report Screen



Parts of the Primary Work Area

The different parts of the Primary Work Area are defined as follows:

Subsection 3.1: Application Window

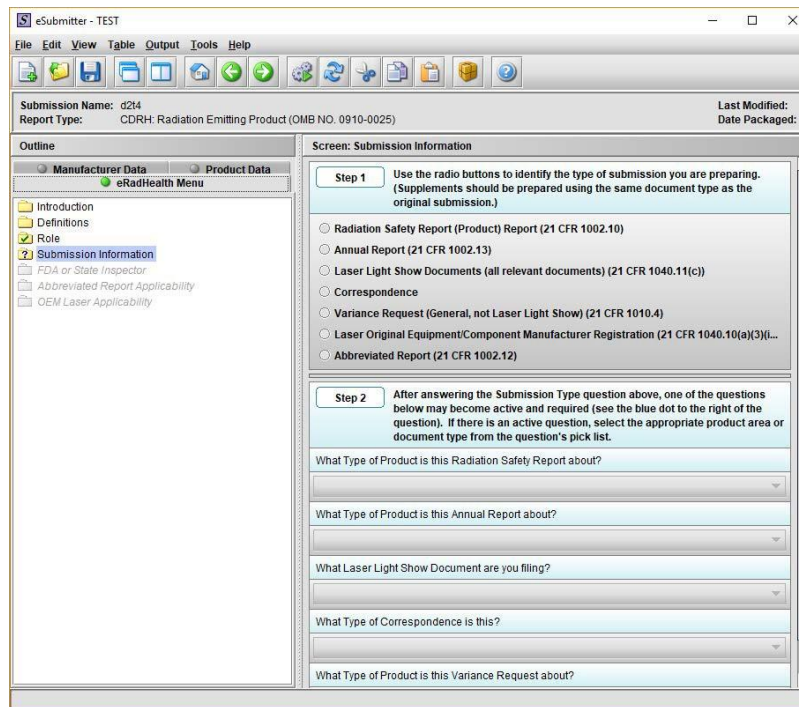
Header Area

Displays the following general information about the open submission:

- **Submission Name** – the name that you created for the report.
- **Report Type** – depends on the type selected when creating the submission in the Create New Submission wizard.
- **Last Modified** – represents the date and time the submission information was last saved to the disk file. The date and time are automatically updated after each save.
- **Date Packaged** – represents the date and time the submission files were generated for transfer to FDA. The date and time are automatically set after the files are packaged for submission.

Outline Area/View




Displays tabs that organize the report into sections (as shown below).



Each tab within the outline has an image to the left of its descriptive text. This image depicts which tab contains the section that is currently displayed within the screen area (i.e., the tab with the highlighted green image).

Each section within the outline contains a folder image to the left of the section text. This folder image depicts the status of required information that is missing from within the question responses of the section. For example:

Subsection 3.1: Application Window

- **Green check mark**  indicates no required information is missing.
- **Blue question mark**  indicates at least one item of required information is missing.
- **No mark**  indicates that the section does not contain any required questions.

Screen Area/View

Displays the questions and responses associated with the selected section in the outline area. There is complete flexibility in maneuvering through the screen area. However, questions should be answered in order. Responses to some questions will determine whether further questions are required or even applicable, which means they may become disabled.

Some questions within the screen area may be required in order for the report to be considered complete. These questions are designated with a blue dot to the right of the question text. A complete list of required information that is currently missing from the report can be accessed by selecting the **Missing Data Report** option on the **Output** menu.

The presence of a scroll bar on the right-hand side of the screen area indicates that the screen extends below the view window. To scroll down to view questions and messages that are below the view window, press the downward scroll arrow.

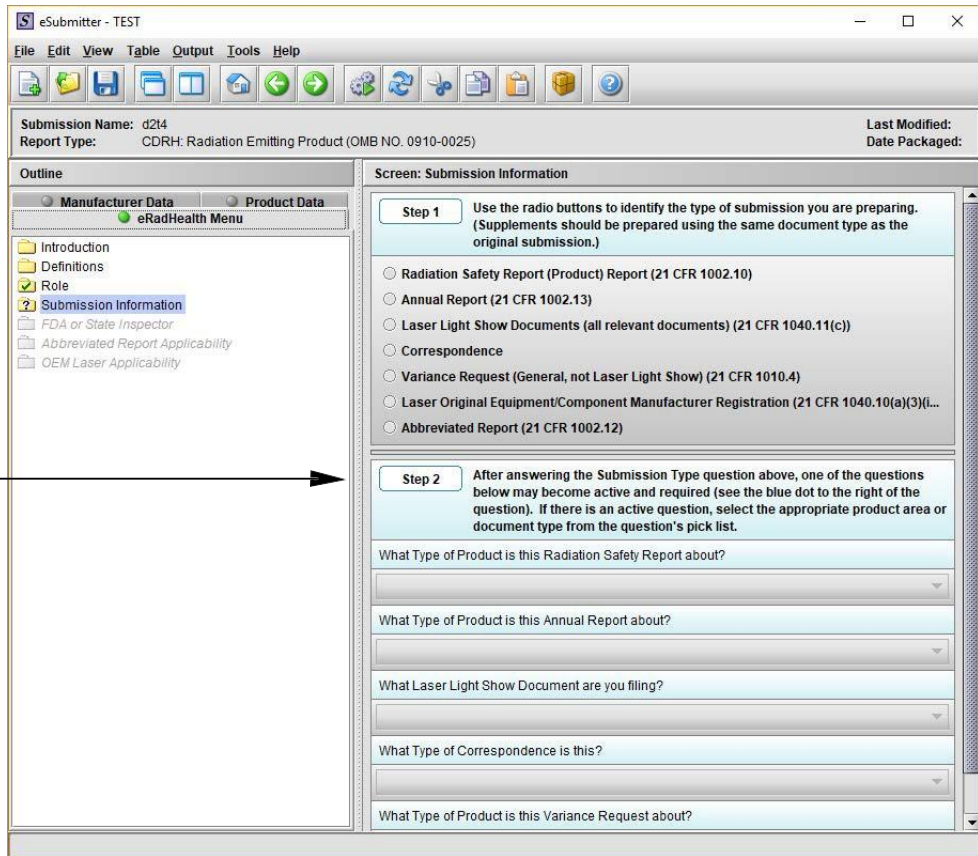
Note: It is recommended that you always scroll down the entire screen to ensure that you have answered all questions for that screen.

Splitter Bar

The splitter bar is the vertical bar between the outline and screens areas in the Expert layout, as shown below. By dragging the bar with the mouse to the left or right you can control the proportion of the window that is allocated to each of the areas. Adjusting this bar may be necessary on smaller monitors in order to improve readability of the text.

Subsection 3.1: Application Window

Splitter Bar



Subsection 3.2: Toolbar







Introduction












The tool bar is a row of buttons that are designed to provide quick access to specific or commonly used commands and options. The tool bar is located below the menu bar.

Note: The screens and information that are accessed through the icons can also be accessed using the following menus: **File**, **Edit**, **View**, and **Help**. However, you must access information for **Output** and **Tools** (with the exception of Package Files for Submission) through the actual menus. For information relating to output and tools functions, refer to pages 43 and 44 respectively.

The buttons on the tool bar are grouped by functionality and are described below:

Tool	Function
	New – Displays the New Submission Dialog box, which allows a new (empty) template to be created.
	Open – Displays the Open Submission Dialog box, which allows an existing template to be selected and opened.
	Save – Saves any changes within the open submission to permanent storage (e.g., to the disk).
	Simple Layout – Selects the simple layout, which displays the current data entry screen and contains basic options for moving forward and backward through the report one screen at a time.
	Expert Layout – Selects the expert layout, which contains the overall outline and current data entry screen side-by-side.
	Home – Takes you to the home screen.

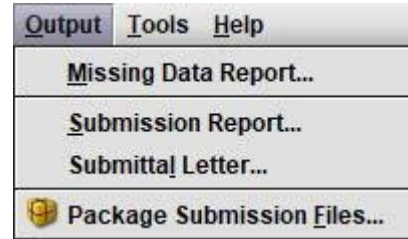
Subsection 3.2: Toolbar

	Previous – Navigates to the previous screen.
	Next – Navigates to the next screen.
	Process Screen Changes – Processes your changes to screens without saving the submission or selecting another node. This option allows you to see how rules impact the form based on the changes made without having to leave the screen.
	Screen Undo – Undoes most recent changes made.
	Cut – Cuts text.
	Copy – Copies text.
	Paste – Pastes text.
	Package Files for Submission – Packages your submission to send to FDA after you have completely answered all required questions. For complete information, see Packaging Submission Files on page 92.
	Help Contents – Displays the Help Menu, which includes the User Manual, Quick Guide, and FAQs.

Subsection 3.3: Menu Bar - Output

Introduction

The **Output** menu includes commands related to the output of reports for submission information. For complete information on getting a submission ready to send to FDA, see Completing a Submission on page 87.



Note: All report outputs are generated as Rich Text and require an application capable of viewing output, such as a WEB browser, the full version of Adobe Acrobat (not Acrobat Reader), or Microsoft Word.

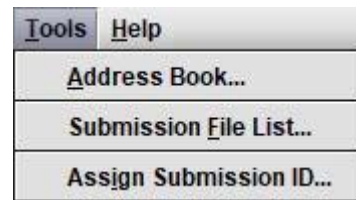
Each command on the Output menu is described below.

Output Menu Commands

Tool	Function
Missing Data Report	Provides a list of required questions that you have not yet answered. The list is provided in Rich Text format. You can save the report file at any time. However, you will not be able to package a submission file to submit to FDA until there is no missing data. For complete information, see Subsection 4.5: Completing a Submission on page 87.
Submission Report	Views/prints out the submission report with your entries in Rich Text.
Submittal Letter	Provides a formatted cover letter in Rich Text for you to sign that identifies your file and must be submitted along with the CD and any hardcopy of the report (if required) to FDA.
Package Files for Submission	Allows you to package files for submission after completing the submission and verifying that there is no information missing. For more information on packaging files for submission, see Subsection 4.5: Completing a Submission on page 87.

Subsection 3.4: Menu Bar -Tools

Introduction Each command on the Tools Menu is described below:

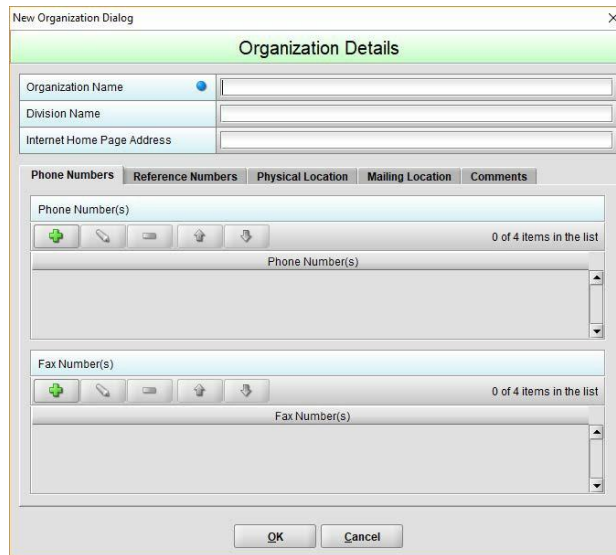


Tools	Function
<p>Address Book</p>	<div data-bbox="537 615 792 1125" data-label="Text"> <p>Displays the <i>Organization/Contact Address Book Dialog</i> box, which provides the ability to maintain the addresses of the pertinent Organizations and Contacts of the manufacturing and corporate facilities associated with your reports.</p> </div> <div data-bbox="803 611 1442 1129" data-label="Image"> </div> <div data-bbox="537 1150 1442 1438" data-label="Text"> <p>You only need to enter each organization name and address once into the Address Book, then select the appropriate entry in response to each question. If the mailing address is the same as the physical address, the physical address can be copied into the mailing address fields. If they are similar but not exactly the same, it can be copied, and then edited. The Address Book will always be accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries.</p> </div> <div data-bbox="537 1476 1442 1654" data-label="Text"> <p>The <i>Organization/Contact Address Book Dialog</i> box contains a list of all the available organizations and a comments area for viewing the comments on the selected establishment. In addition, if you scroll across the address list, you'll see fields containing basic identifier information about each organization.</p> </div> <div data-bbox="537 1692 1339 1766" data-label="Text"> <p>Radio buttons control this display as by <i>View by Organization/Contact</i> or <i>View by Contact Only</i>.</p> </div> <div data-bbox="537 1803 1349 1877" data-label="Text"> <p>The <i>View by Organization/Contact</i> has the options (New, Edit, Delete, and Close) in this dialog box are described below:</p> </div>

Subsection 3.4: Menu Bar -Tools

New

Displays the *New Organization Dialog* box, which allows a new organization to be created. Below is an example. Enter information in the fields to identify a particular organization.



The screenshot shows a dialog box titled "New Organization Dialog" with a close button (X) in the top right corner. The main title bar is "Organization Details". Below the title bar are three input fields: "Organization Name", "Division Name", and "Internet Home Page Address". Below these fields are five tabs: "Phone Numbers", "Reference Numbers", "Physical Location", "Mailing Location", and "Comments". The "Phone Numbers" tab is currently selected. It contains two sections: "Phone Number(s)" and "Fax Number(s)". Each section has a toolbar with a green plus icon, a trash icon, a minus icon, and up/down arrow icons. Below each toolbar is a list box showing "0 of 4 items in the list" and a "Phone Number(s)" or "Fax Number(s)" label. At the bottom of the dialog are "OK" and "Cancel" buttons.

⇒ Click the **Reference Numbers** tab to enter the reference numbers associated to the organization is physically located. See below.



The screenshot shows the "Reference Numbers" tab selected. It contains a table with the following fields:

Reference Numbers	
FDA Establishment Identifier (FEI):	<input type="text"/>
Central File Number (CFN):	<input type="text"/>
D&B D-U-N-S Number:	<input type="text"/>
Registration Number:	<input type="text"/>
Owner/Operator Number:	<input type="text"/>
Help Finding Registration and Owner/Operator Numbers for Devices	
Help Finding Blood Establishment Registration Numbers	

⇒ Click the **Physical Location** tab to enter address information for where the organization is physically located. See below.



The screenshot shows the "Physical Location" tab selected. It contains a table with the following fields:

Address	
Country:	<input type="radio"/> United States of America <input type="radio"/> Other (select below) <input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State, Province, or Territory:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>

Subsection 3.4: Menu Bar -Tools

⇒Click the **Mailing Location** tab to enter address information for the mailing address of the organization.



The screenshot shows a software window with five tabs: Phone Numbers, Reference Numbers, Physical Location, Mailing Location (selected), and Comments. Below the tabs is a text area with the prompt "Copy the physical location to the mailing location" and a "Copy Address" button. Underneath is an "Address" section with the following fields: "Country:" with radio buttons for "United States of America" and "Other (select below)"; "Address - Line 1:"; "Address - Line 2:"; "City:"; "State, Province, or Territory:" with a dropdown arrow; and "Post Office or Zip Code:".

⇒Click **Copy Address** if the mailing location is the same as the physical location of the organization. The information is automatically copied into the address fields (as shown above). However, if the mailing location differs drastically from the physical location, you must manually enter the information.

⇒When you are finished with the addresses, click **OK** to save your edits or click **Cancel** to ignore all edits. You return to the *Organization/Contact Address Book Dialog* box.

⇒Click the **Comments** tab to enter comment information for the organization.



The screenshot shows the same software window with the "Comments" tab selected. It features a large text area labeled "Organization Comments" and a small note pad icon button on the right side.

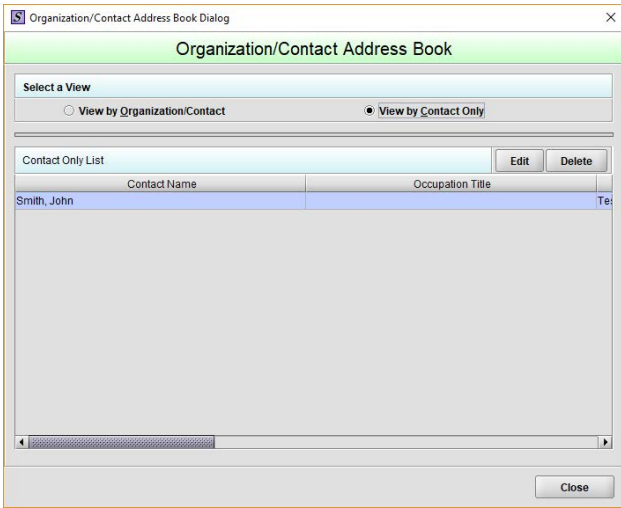
⇒When you click the note pad icon a text entry pop up is displayed.



⇒When you are finished with the comments, click **OK** to save your edits or click **Cancel** to ignore all edits. You return to the *New Organization Dialog* box.

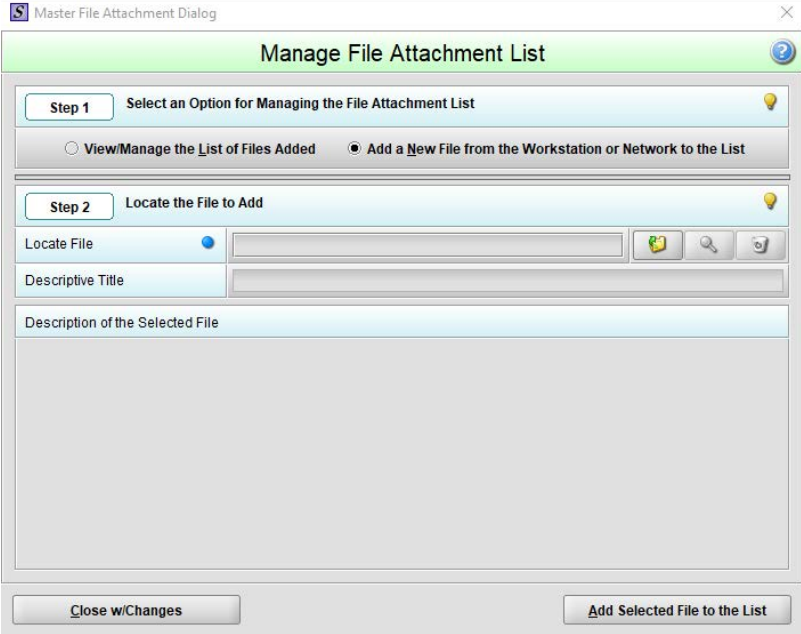
Subsection 3.4: Menu Bar -Tools

Edit	Displays the <i>Edit Organization Dialog</i> box, which allows the selected establishment information to be changed. (You enter information in this dialog box in the same manner as the <i>New Organization Dialog</i> box.)
Delete	Deletes the selected contact from the list.

Tools	Function
View by Contact Only	<p>Displays the <i>Organization/Contact Address Book Dialog</i> box, already entered individually. The View by Contact Only has the options (Edit, Delete, and Close) in this dialog box are described below:</p> 

Edit	Displays the <i>Edit Contact Dialog</i> box, which allows the selected contact information to be changed.
Delete	Deletes the selected contact from the list.
Close	Closes the dialog box.

Subsection 3.4: Menu Bar -Tools

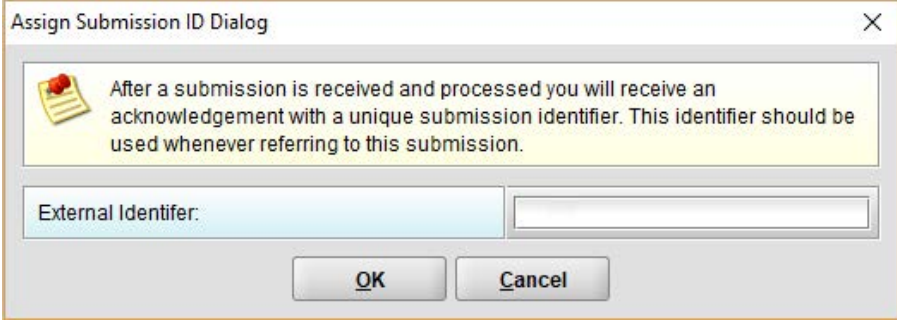
Tools	Function
<p>Submission File List</p>	<p>Displays the <i>Master File Attachment Dialog</i> box, which allows you to manage the file information to be attached for use across questions in the submission. Default radio button is <i>Add a New File from the Workstation or the Network to the List</i>.</p>  <p>Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). If you did not set your file viewer under User Preferences, the first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 21.</p> <p>Note: The file list is specific to the submission that is currently open, retained nor accessible for future reports.</p> <p>The <i>Master File Attachment Dialog</i> box manages the file attachment information related to the open submission. The dialog box contains a list of all the attached files that are currently available, an area for general information on the selected file, and options for managing the list. The file list displays the following for each:</p>

Subsection 3.4: Menu Bar -Tools

	<ul style="list-style-type: none"> • Descriptive title • Physical file name • Number of questions that currently reference the file as an attachment • File date • File size • Path to the file location <p>The options provided in the dialog box are described below:</p>
--	---

Add a New File	Allows you to add a new file to the Master File Attachment list for later use as a question response. For instructions on how to attach files as a question response, see How to Attach a File to an Attachment Question Type, beginning on page 62.
View/ Manage File List	Allows you to manage the existing documents in the list of files displayed in Step 2. The options available for managing the list of existing files include View, Edit, Delete, and Close. These options are described below.
View	Displays the selected file within the specified PDF viewer.
Edit	Displays the Edit File Dialog box, which allows the selected file title and general description to be changed.
Delete	Deletes the selected file from the list.
Close w/ Changes	Closes the dialog box and saves the changes made to the Master File Attachment list.

Subsection 3.4: Menu Bar -Tools

Tools	Function
<p>Assign Submission ID</p>	<p>Allows you to enter an FDA-related identifier to a submission. After you have sent the submission to the FDA for processing and if you have received a unique identifier, you may store that FDA assigned identifier in the submission for tracking purposes. For complete information on preparing a submission, see page 51.</p> <p>To enter a Report ID:</p> <ul style="list-style-type: none"> ⇒ Select Assign Submission ID from Tools on the Menu bar. You see the Assign Submission ID dialog box (see below). ⇒ Enter the unique identifier assigned by FDA. ⇒ If you are satisfied with your entry, click OK. Or, click Cancel to close the dialog box without making any changes. 

Section 4: Preparing a Submission

Contents

This section contains the following topics:

Topic	See Page
Entering Submission Information	52
Question Types	54
▶ Address and Contact Information	54
▶ Option Lists	57
▶ File Attachments	61
▶ Guidance Documents	67
▶ Text Fields and Messages	70
▶ Product Codes	72
▶ Standards	78
▶ Sections as Tables	80
Relationships Across Screens	81
Saving Submission Entries or Changes	86
Completing a Submission	87
Completing a Submission (Packaging Submission Files)	92

Subsection 4.1: Entering Submission Information

Introduction

Entering information for a submission requires stepping through the form and answering questions. If you use the simple layout, you progress through the form screen by screen, ensuring that you have filled in all appropriate responses. If you use the expert layout, you progress through the outline sections of the form, activate each section to load the section questions and responses, and ensure that you have filled in all appropriate responses. You may also use the green navigation arrows located in the tool bar to move through the submission in expert view.

Note: For the purpose of this guide, all graphics are in the **expert view**. Also, information marked with a **blue dot** is required.

For additional information on the simple and expert layouts, see Interface on page 34. It is strongly recommended that you follow the order of the sections as they are listed in the outline. The order has been set up to represent the most logical progression through the submission form. This is especially important for first-time users who are less familiar with the application to ensure you have filled in all appropriate responses.

Note: It is recommended that you always scroll down the entire screen to ensure that you have answered all questions on the page.

Entering Responses into the Submission

To enter responses into the submission, follow the instructions below.

Action	Graphic
1. The eSubmitter application must be open on your computer desktop, and a submission must be open. If the application and a submission are not open, see the instructions beginning on page 8.	
2. Navigate through the submission as follows: <ul style="list-style-type: none"><li data-bbox="524 1612 1195 1717">• If you are in the simple layout, use the buttons on the navigation bar to advance to next/return to previous screen.<li data-bbox="524 1755 1195 1860">• If you are in the expert layout, use the outline pane, and activate each section to load the screen or the navigation arrows located on the tool bar.	

Subsection 4.1: Entering Submission Information



3. Provide a response to the question(s) on the screen. The response required depends on the type of question.
-

Question Types The eSubmitter tool uses several different types of questions to capture all the information that is required for a specific report. The response that you enter depends on the type of question used in your particular report. For example, to answer a specific question, you may be required to select a response from a drop-down box, type in text, attach a separate PDF file, select a check box, or provide contact information.

The following subsections describe each of the different question types and include examples of their respective responses.

Note: You may not see all of these types of questions in one particular report. The purpose of this section is to provide a brief overview of all of the different question types that are used in the eSubmitter software.

Subsection 4.2.1: Question Types – Address and Contact Information

<p>Address</p>	<p>This question type requires that you enter the address and phone numbers of your organization. You enter the information in text fields and make selections using drop-down menus and clicking option buttons. An example is shown below. Other types of address questions are Contact and Multi-Part Address, which will be discussed below.</p> 
<p>Contact (Simple)</p>	<p>This question type requires that you type contact information (first name, last name, etc.) in text fields. Entries may or may not be required. The figure below shows an example of a simple contact question with the first name, last name, and email address as required fields (as indicated by the blue dots).</p> 
<p>Contact (Multi-Part)</p>	<p>This question type contains multiple sections that you need to complete (indicated by the tabs: Contact Information, Establishment Identification, Physical Location, and Mailing</p>

Subsection 4.2.1: Question Types – Address and Contact Information

Location). For this question type, you may enter contact information (first name, last name, etc.) directly into text fields, or you may copy this information from the Contact Book. When you enter the information directly (without using the Contact Book), the contact information is only saved for the submission. Copying the information from the Contact Book saves time for data entry because the information is automatically copied into the question. Information in the Contact and Address Books requires that you only enter the data once and reuse it across multiple submissions.

You can also copy information from the question into the Contact or Address Books if you have already begun filling in the question fields directly.

The figure below shows an example of a multi-part contact question.

The screenshot shows a form with four tabs: 'Contact Identification', 'Organization Identification', 'Physical Location', and 'Mailing Location'. The 'Contact Identification' tab is selected. Below the tabs is a section titled 'Contact' containing several text input fields: 'Title (e.g., Mr., Ms.)', 'First/Given Name', 'Middle Name', 'Last Name', 'Suffix (e.g., Sr, Jr, III)', 'Degree(s) (e.g., PhD, JD)', 'Occupation Title', and 'Email Address'. A blue circular icon is visible next to the 'First/Given Name', 'Last Name', and 'Email Address' fields. An arrow labeled 'Tabs' points to the tab headers.

Copy Information from Contact Book into Question

To copy information from the Contact Book into the Contact question type, follow the instructions below.

Action

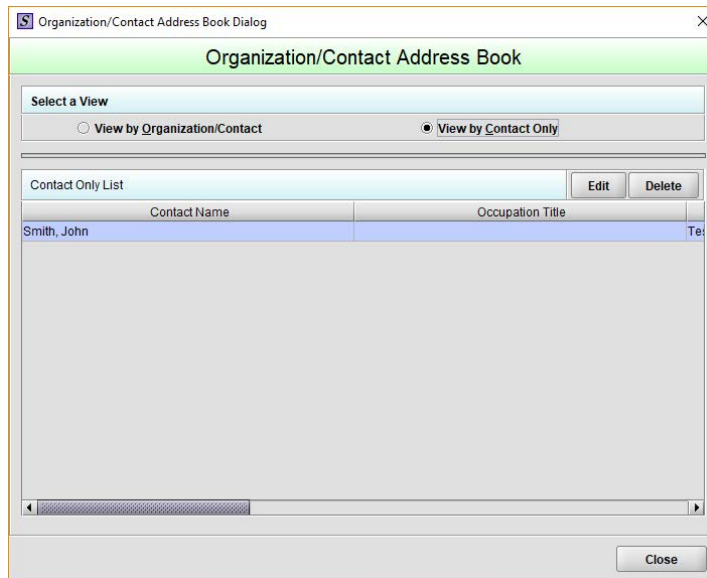
Graphic

1. Click the **Copy from Contact Book** icon in the question. The Contact List Dialog box is displayed, as shown below.

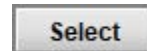


Subsection 4.2.1: Question Types – Address and Contact Information

Contact List Dialog Box



2. Click to highlight and select the desired contact.
3. Click **Select**. The contact information is automatically populated in the different entry areas (within each applicable tab).
4. If the information is not exactly the same, you can edit the information in the question fields after you have copied it.
5. To see the other information, click on the desired tab. If you copied the contact information from the Contact Book, the information for these tabs will be completed as well.
6. For more information about Contact Books, see page 54.



Copy Information to Contact Book from Question

To copy information to the Contact Book from the Contact question type, follow the instructions below. **Note:** An Establishment must be associated.

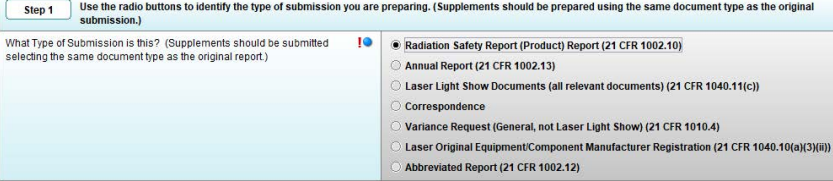
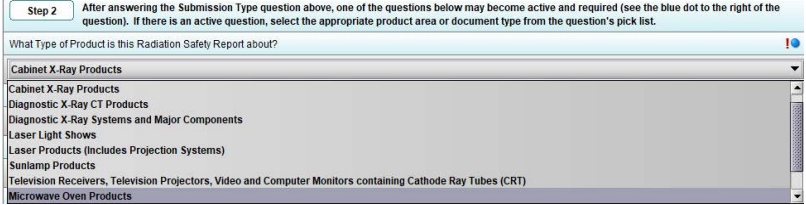
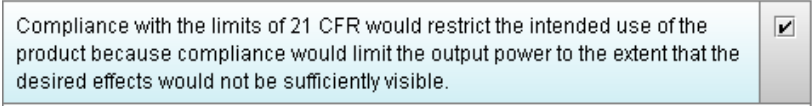
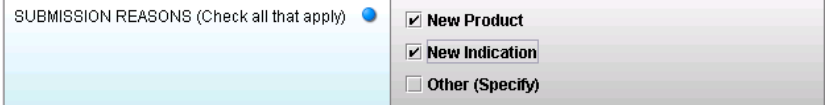
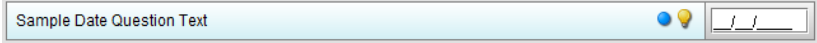
Action

Graphic

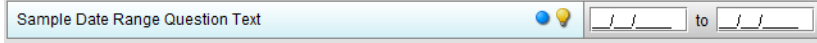

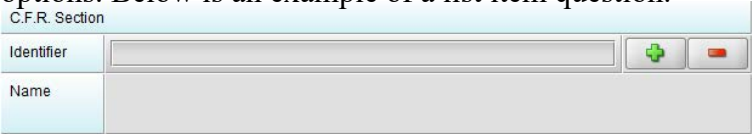
1. Click the **Copy to Contact Book** icon in the question. The Contact List Dialog box is displayed, as shown below, with the entry added.



Subsection 4.2.2: Question Types – Option Lists

<p>Radio Button</p>	<p>This question type requires that you click on the radio button to select a question response. Only one response can be selected. See the example below.</p> 
<p>Drop-Down Menu</p>	<p>This question type requires that you select a response from a list of entries that appear after you click the box with the down arrow (▼). Below is an example of a question with a drop-down menu.</p> 
<p>Check Box</p>	<p>This question type requires that you click on the box to select or clear the check mark to answer a question. See the example below.</p> 
<p>Check Box Group</p>	<p>This question type requires that you click on the box(es) to select or clear the check mark(s) to answer a question. Multiple responses can be selected. See the example below.</p> 
<p>Date</p>	<p>This question type requires that you type in a date, using mm/dd/yyyy format as a response. See the example below.</p> 

Subsection 4.2.2: Question Types – Option Lists

<p>Date Range</p>	<p>This question type requires that you type in a date range, using mm/dd/yyyy format as a response. See the example below.</p> 
<p>Numeric Spinner</p>	<p>This question type allows you to use the up and down arrows to select a number. Alternatively, you may enter a number directly into the field. See the example below.</p> 
<p>List Item</p>	<p>This question type allows you to select an item from a list of options. Below is an example of a list item question.</p> 

Access the List of Available Options

To access the list of available options, follow the instructions below.

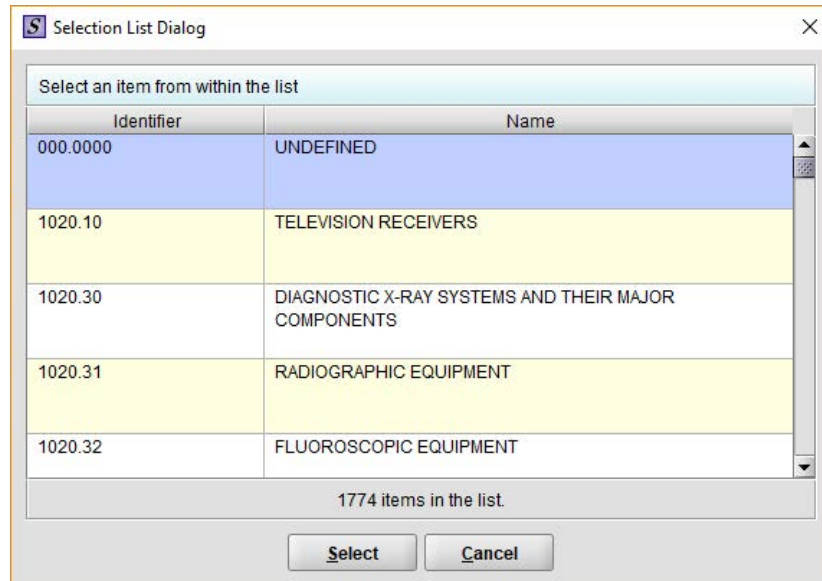
Action

Graphic

1. Click the **Select Item** icon. A Selection List Dialog box is displayed (as shown below).



Selection List Dialog Box





2. Click to select (highlight) the desired option.

Subsection 4.2.2: Question Types – Option Lists

- Click the **Select** button. The Selection List Dialog box closes, and you return to the open submission with the list item question showing your selection (as shown below).









C.F.R. Section	
Identifier	1020.10  
Name	TELEVISION RECEIVERS

- If you wish to change your response, click the **delete** icon. Your response selection is deleted from the question.





- Repeat steps 1 through 3 to make another selection.

Table	<p>This question type allows you to select from a list or add text items that are then placed in a table. Below is an example.</p> <div style="border: 1px solid gray; padding: 5px;"> <p>Describe the characteristics, operation, and location of the main power control.</p> <div style="border: 1px solid gray; padding: 2px;">       0 items in the list </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Title</th> <th style="width: 33%;">Name</th> <th style="width: 17%;">Dal</th> <th style="width: 17%;">Path</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> </div>	Title	Name	Dal	Path				
Title	Name	Dal	Path						

Select multiple options or enter text responses into a Table

To select from a list of options or to enter text responses into a table question type, follow the instructions below.

	Action	Graphic
1. Click the Add icon.		
2. You will be prompted to either select from a list of options or enter a response into a text field.		
3. If you wish to change your response, select (highlight) the option in the table and click the delete icon. The selection is deleted from the question list.		

Subsection 4.2.2: Question Types – Option Lists

Action	Graphic
4. You may have the option on some to change the name by selecting the Pencil icon	
5. Repeat steps 1 and 2 to make another selection or enter text responses into the table.	

Subsection 4.2.3: Question Types – File Attachments

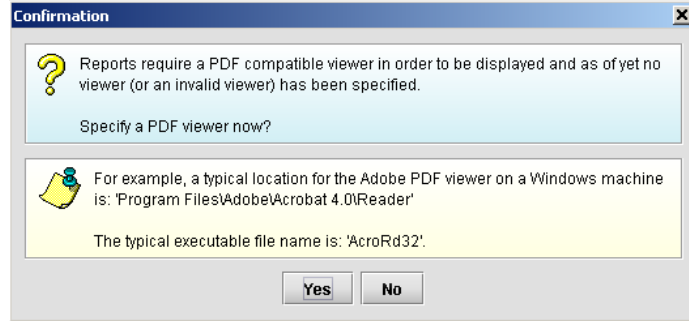
File Attachment

Please see [Section 5 FDA Recommendations for PDF File Specifications](#) to ensure you are meeting the FDA recommendations for electronic files submitted and archived.

This question type allows you to attach a file as a response. The question may contain a text editor that allows or requires you to type additional information. In addition, this editor may be a Rich Text Editor, which allows you to format what you type (bold, underline), run spell check, or insert a table. You may use this area to provide descriptive information or clarification, such as “see page 15 of the attached user manual.” You may be required to enter the attachment or provide the descriptive text.

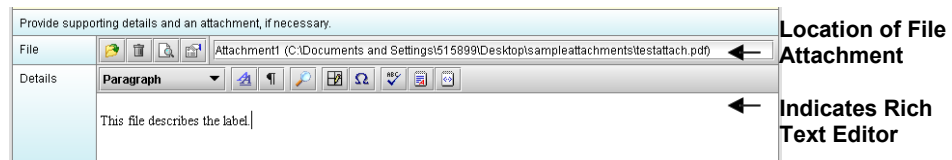
Note that the question itself may be restricted to only allow certain file types to be attached (e.g., PDF only or a combination, such as PDF and/or Excel file types only).

Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). The first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. (See below).



Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 21.

Below is an example of a file attachment question with a response properly attached. See instructions for correctly attaching files in the subsequent section.



Subsection 4.2.3: Question Types – File Attachments

How to Attach a File to an Attachment Question Type

To attach a file as a response to an attachment question in eSubmitter, follow the instructions outlined below.

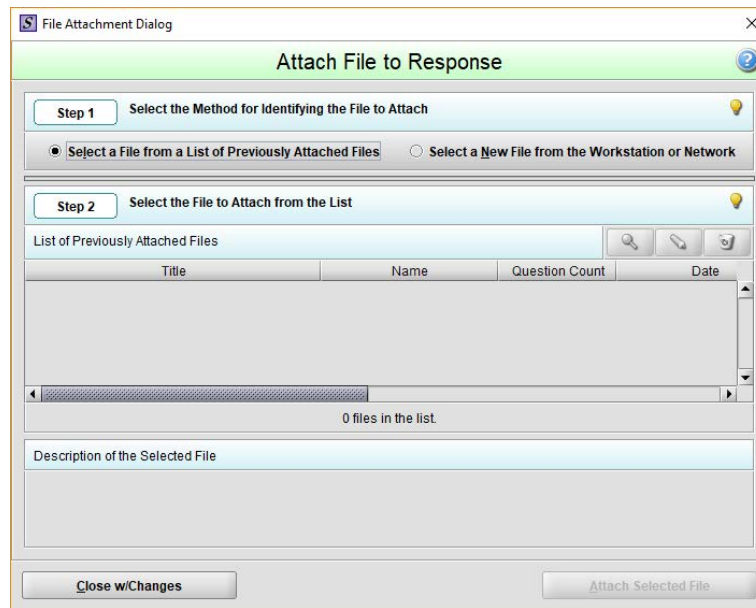
Action

Graphic

1. Click the **Add File** icon to select the desired file to attach as the question response. The File Attachment Dialog wizard is displayed (as shown below).



File Attachment Dialog Box



2. **Step 1: Select the Method for Identifying the File to Attach.**

In this step, choose the desired method for selecting the file to attach. The options are:

1. Choose a previously attached file from the master list of previously attached files

OR

2. Select a new file from your computer or a network drive that has not been previously attached to the submission.

Note: The wizard defaults to the method “Select a File from a List of Previously Attached Files” if the master file list contains any files to choose from. If

Subsection 4.2.3: Question Types – File Attachments

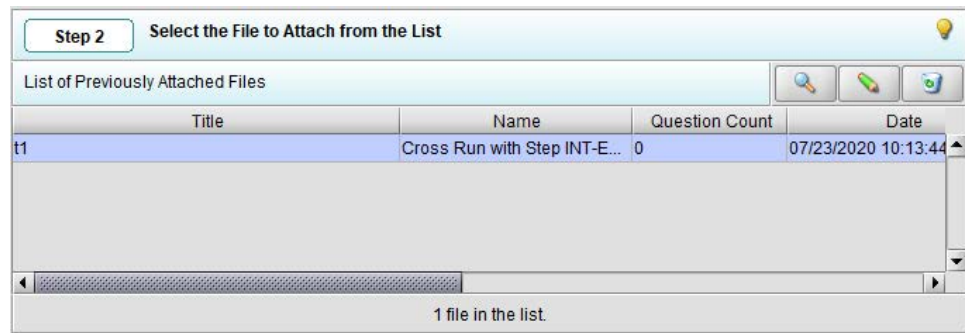
there are no files in the master file list, it will default to the method “Select a New File from the Workstation or Network”.

If you would like to navigate to a location on your computer and select a new file, click the radio button to change the response in Step 1 to “Select a New File from the Workstation or Network”.

- Step 2: Select the File to Attach According to the Method Chosen** -- Select a File from a List of Previously Attached Files.

If the file can be located in the list of previously attached files, select (highlight) the file from the list.

Select a File from a List of Previously Attached Files



- Once a file in the list is highlighted, the **Attach Selected File** button is activated in the bottom right side of the dialog box.



Click the **Attach Selected File** button to properly attach the selected file to the question response.

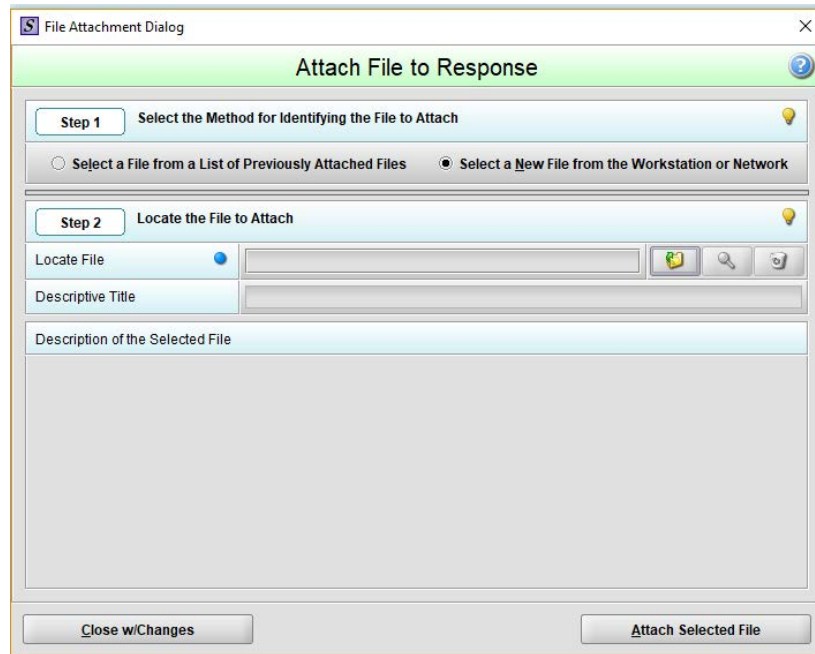
- Step 2: Select the File to Attach According to the Method Chosen** -- Select a New File from the Workstation or Network.

If the file cannot be located in the master list, then the method chosen in Step 1 must be “Select a New File from the Workstation or Network”.

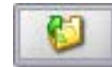
- Step 2** of the File Attachment dialog changes to correspond with the method chosen (as shown below).
-

Subsection 4.2.3: Question Types – File Attachments

Select a New File from the Workstation or Network

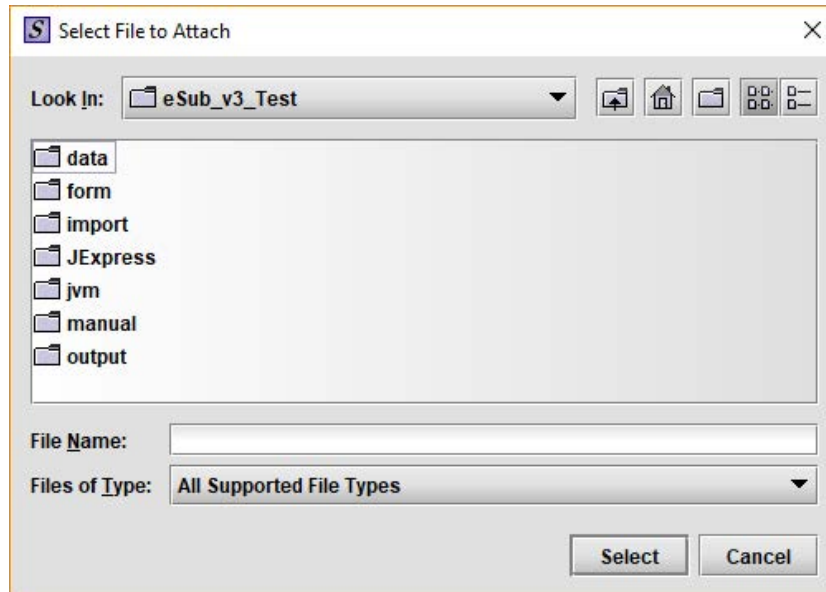


7. Click the **file folder** icon to the right of the **Locate File** field.



You will see a Select File to Attach dialog box as shown below.

Select File Dialog Box



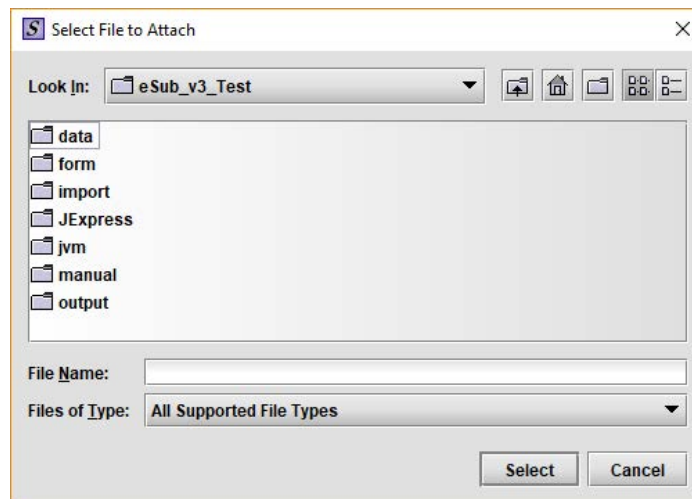
Subsection 4.2.3: Question Types – File Attachments

- Verify that the correct file type is selected in the **Files of Type** drop down located below the **File Name** field. Only those files of the type chosen will appear in the display pane for you to select. The **Files of Type** is defaulted to **Adobe Acrobat Files (.pdf)**.

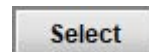
Note: The **Files of Type** drop-down field may not be enabled if the question has been set to restrict the response to only allow a particular file type (e.g., PDF only).

- Click the **Look In** drop-down menu to locate the drive, such as Local Disk (C:), or folder where the file you wish to attach is stored.
- When you locate the desired file, click to select it (highlight). The name of the file appears in **File Name** (as shown below).

Select File
Dialog Box –
File Selected



- Click **Select**. The Select File to Attach dialog box closes, and you return to the File Attachment dialog box.
- Enter a title in **Descriptive Title** (required entry) and a description in **Description of Selected File**, if desired.



Subsection 4.2.3: Question Types – File Attachments

13. Click **Attach Selected File**. You return to the submission.

Multiple File Attachments

This question type allows you to attach multiple files as a response. Below is an example of an attachment question with a file attachment included. In the image below, the green plus sign is still enabled after attaching a file, indicating that additional files may be attached as the response.

To attach multiple PDF files to an attachment question, follow the same instructions listed under How to Attach a File to an Attachment Question Type beginning on page 62.

List of Previously Attached Files			
Title	Name	Question Count	Date
Doc1	eSubmitter Download and I...	1	10/16/2020 01:08:33
doc1a	CBER eSubmitter Electroni...	1	10/20/2020 10:15:28
doc1b	CBER eSubmitter Electroni...	1	10/16/2020 08:48:21
fov2	ORA Style guide.pdf	1	12/13/2018 08:39:52

Scroll Bar to view additional details on files

Subsection 4.2.4: Question Types – Guidance Documents

Guidance Documents	<p>This question type allows you to select the guidance documents that you used to prepare your submission, as well as provides space for you to add supporting text if necessary. Below is an example of a guidance document question.</p>
---------------------------	---

Please enter all referenced Guidance Documents.

+
–
🔍

0 items in the list

Document Title	Office	Division
(Empty table area)		

Select a Guidance Document

To select a guidance document, follow the instructions below.

Action

Graphic

1. Click the **Add Guidance** icon. The Guidance Document Filter Dialog box is displayed (as shown below).



Guidance Document Filter Dialog Box

Guidance Document Filter Dialog

Provide Guidance Document filter criteria (keywords)

• Title Office **CDER** Division

Guidance Documents matching the specified filter criteria View Guidance...

Title	Office	Division	
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis	CDER		http://www.fda.gov/cd
Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds Developing Products for Treatment	CDER		http://www.fda.gov/cd
Acceptance of Foreign Clinical Studies; Guidance for Industry	CDER		http://www.fda.gov/cd
Guidance for Industry; Collection of Race and Ethnicity Data in Clinical Trials	CDER		http://www.fda.gov/cd

7 Guidance Documents in the filtered list.

Guidance Documents currently selected View Guidance...

Title	Office	Division	
Guidance for Industry; Collection of Race and Ethnicity Data in Clinical Trials	CDER		http://www.fda.gov/cd

1 Guidance Document in the selected list.

Clear Filter
Select
Delete
OK
Cancel

Subsection 4.2.4: Question Types – Guidance Documents

2. On this dialog box, you have several options for searching for a particular guidance document:
- In the **Title** text box, you can type the title of the desired document (if you know what it is).
 - If you do not know the title of the document, select the applicable office from the **Office** list box.
 - On the **Division** list box, select the desired division.
 - Click **Clear Filter** to delete your selections and begin a new search.

Clear Filter

3. Depending on which method you used, one or more guidance documents will appear in the **Guidance Documents matching the specified filter criteria** area of the screen

4. Use the scroll bar to see information about the found guidance documents.

5. If you are connected to the Internet and have Adobe Acrobat installed, click to select a desired document, and click **View Guidance** to see the selection.

View Guidance...

6. To move a guidance document to **Guidance Documents currently selected** area of the screen:

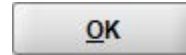
- Click to select (highlight) a particular guidance document.
- Click **Select**. The selected document appears in **Guidance Documents currently selected** area of the screen.
- Repeat the above two items for each desired guidance document.
- Click **Delete** to remove a guidance document from your selection.

Select

Delete

Subsection 4.2.4: Question Types – Guidance Documents

7. Click **OK** when you have made your selections.



You return to the guidance document question with your selection appearing. Below is an example of a guidance document question containing a response.



Guidance Document Containing a Response

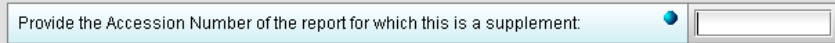
Please enter all referenced Guidance Documents.


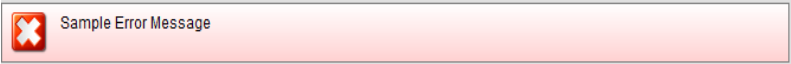
1 item in the list

Document Title	Office	Division	
Expedited Review of Premarket Submissions for Devices - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cdrh/m

Subsection 4.2.5: Question Types – Text Fields and Messages


Memo (Multi Line Text)	<p>This question type provides an area for you to enter several lines of text (as shown below).</p> <div data-bbox="605 447 1391 621"></div> <p>The question may contain a Rich Text Editor which allows you to format what you type (bold, underline), run spell check, or insert a table. The tool bar for the Rich Text Editor will appear after you click in the text area to begin typing.</p> <div data-bbox="605 831 1391 968"></div>
---------------------------------------	--

Text, Single Line	<p>This question type allows you to type in text as a response. Below shows an example of a text question.</p> <div data-bbox="548 1178 1377 1220"></div>
----------------------------------	---


Message	<p>This question type provides information to you as you complete a submission. You may see several different types of messages as you progress through your submission. Different examples of the message types are listed below:</p> <ul style="list-style-type: none"><li data-bbox="605 1507 967 1539">• Information Message <div data-bbox="605 1570 1391 1633"></div> <ul style="list-style-type: none"><li data-bbox="605 1675 878 1707">• Error Message <div data-bbox="605 1738 1391 1801"></div>
----------------	--

Subsection 4.2.5: Question Types – Text Fields and Messages


- **Stop Message**

 Unfortunately, this software currently only supports submissions for in vitro diagnostic devices, radiation emitting products, and medical device adverse event reporting. For all other submissions, please check back at a later date for information on additional submissions that will be supported by this software. Please email any questions or comments to the CeSub team at: cdrhesub@cdrh.fda.gov. Be sure to include your name, company name and contact information in the email. Thank you again for using our electronic product reporting software.


- **Note Message**

 Contains Information on the Applicable Contacts

- **Confirmation Message**

 Are you sure you want to delete this item?

- **Warning Message**

 Any changes made will be lost if they are not saved.
Selecting the Cancel button will prevent the operation from continuing (i.e., closing the report template).

- **Missing Data Message**

Screen Navigation Dialog







Select an option

I would like to add/select a new Product

Continue to the Next screen


OK Cancel

Subsection 4.2.6: Question Types – Product Codes

Product Code (Single)	<p>This question type allows you to search for and then identify the product code that is assigned to your product or device. If applicable, you are able to search for the device class, device panel, and particular CFR section. The response to this question is for a single product code. Below is an example of a product code question.</p> <p>Note: The Product Code is specific to those filing with the Center for Devices and Radiological Health.</p> <div style="border: 1px solid black; padding: 5px;"> <p>Choose the product code for this submission.</p> <table border="1"> <tr> <td>Product Code</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>Product Code Name</td> <td colspan="3"></td> </tr> <tr> <td>Device Class</td> <td colspan="3"></td> </tr> <tr> <td>Classification Panel</td> <td colspan="3"></td> </tr> <tr> <td>C.F.R. Section</td> <td colspan="3"></td> </tr> <tr> <td colspan="4">Add any other product codes that are applicable to this submission.</td> </tr> </table> </div>	Product Code	<input type="text"/>			Product Code Name				Device Class				Classification Panel				C.F.R. Section				Add any other product codes that are applicable to this submission.			
Product Code	<input type="text"/>																								
Product Code Name																									
Device Class																									
Classification Panel																									
C.F.R. Section																									
Add any other product codes that are applicable to this submission.																									


Enter a Three-Letter Code in the Product Code Question

To enter a three-letter code in the product code question, follow the instructions below:

- If you know the three-letter code assigned to your product/device, enter it in the text field. The remaining fields are automatically filled in for you.
- If you wish to remove your entry, click the **delete** icon ().
- If you do not know the three-letter code, see the instructions below to search for the code.
- If you are selecting a product code for a radiation emitting product and do not see an appropriate code, enter RZZ.

Search for a Three-Letter Code by Keyword



To search for a three-letter code by keyword, follow the instructions below:

Action	Graphic
1. Click the Select Item icon. A Product Code Filter Dialog box is displayed.	


Subsection 4.2.6: Question Types – Product Codes



Product Code Filter Dialog Box

The screenshot shows the 'Product Code Filter Dialog' window. It has a title bar with a close button. The main area is divided into two sections. The top section, 'Provide Product Code filter criteria', contains several input fields: a text box for 'Product Code Name (keyword search)', a dropdown menu for 'Device Class', another dropdown for 'Classification Panel', and a 'C.F.R. Section' section with an 'Identifier' text box and a 'Name' text box. There are also '+' and '-' icons next to the Identifier field. The bottom section, 'Matching Product Codes', is a table with columns for 'Product Code', 'Product Code Name', 'Device Class', and 'Cl:'. Below the table, it displays '0 Product Codes in the list.' At the bottom of the dialog are three buttons: 'Clear Filter', 'Select', and 'Cancel'.

2. Enter a keyword to search the database. You will be provided a list of product codes from which to choose in the **Matching Product Codes** portion of the dialog box.
3. To further refine your search, **if desired**:
 - Click the **Device Class** drop-down list and make a selection.
 - Click the **Classification Panel** drop-down list and make a selection.
 - Click the **Select Item** icon () next to the Identifier (under C.F.R. Selection) and make a selection.
 - Click  to remove entries and start the search over again.

Subsection 4.2.6: Question Types – Product Codes


- Click to highlight the best match to your product/device, and click . You return to the submission screen and the product code question. The remaining fields in the product code question are filled in for you (as shown below).

Choose the product code for this submission.	
Product Code	BRX  
Product Code Name	STOOL, ANESTHESIA
Device Class	CLASS I
Classification Panel	73-ANESTHESIOLOGY
C.F.R. Section	868.6700 - ANESTHESIA STOOL.

<p>Product Codes (Multiple)</p>	<p>This question type allows you to identify other product codes applicable to the submission. Below is an example of a multiple product code question.</p> <div style="border: 1px solid gray; padding: 5px;"> <table border="1"> <thead> <tr> <th colspan="4" style="text-align: right;">2 items in the list</th> </tr> <tr> <th>Product Code</th> <th>Product Code Name</th> <th>Device Class</th> <th>Classification Panel</th> </tr> </thead> <tbody> <tr> <td>REJ</td> <td>LASER CHILDREN'S TOY/NOVELTY PRODUCT</td> <td>UNCLASSIFIED</td> <td>RADIOLOGICAL HEAL</td> </tr> <tr> <td>LKW</td> <td>LASER, NEUROSURGICAL</td> <td>CLASS III</td> <td>84-NEUROLOGY</td> </tr> </tbody> </table> </div>	2 items in the list				Product Code	Product Code Name	Device Class	Classification Panel	REJ	LASER CHILDREN'S TOY/NOVELTY PRODUCT	UNCLASSIFIED	RADIOLOGICAL HEAL	LKW	LASER, NEUROSURGICAL	CLASS III	84-NEUROLOGY
2 items in the list																	
Product Code	Product Code Name	Device Class	Classification Panel														
REJ	LASER CHILDREN'S TOY/NOVELTY PRODUCT	UNCLASSIFIED	RADIOLOGICAL HEAL														
LKW	LASER, NEUROSURGICAL	CLASS III	84-NEUROLOGY														

Add Product Codes

To add product codes, follow the instructions below:

- | Action | Graphic |
|--|---|
| 1. Click the Add Product Code icon. You see the Product Codes Filter Dialog box (as shown below). |  |

Subsection 4.2.6: Question Types – Product Codes

Product Code Filter Dialog Box

2. Enter **Product Code** and **Product Code Name** in the appropriate sections.
3. Click **OK**.



Enter Multiple Three-Letter Codes in the Product Code Question

To enter multiple three-letter codes in the product code question, follow the instructions below:

Note: The Product Code is specific to those filing with the Center for Devices and Radiological Health.

Action

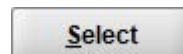
Graphic

1. If you know the three-letter code assigned to your product/device, enter it in the **Product Code** text box. You see the product code/device appear in **Product Codes matching the specified filter criteria** (as shown below).

Subsection 4.2.6: Question Types – Product Codes

Product Codes matching the specified filter criteria			
Product Code	Product Code Name	Device Class	Classification
BRT	RESTRAINT, PATIENT, CONDUCTIVE	CLASS I	80-GENERAL H
BRW	PROTECTOR, DENTAL	CLASS I	73-ANESTHES

2. Click **Select**. The product/device appears in **Product Codes currently selected** (as shown below).



Product Codes currently selected			
Product Code	Product Code Name	Device Class	Classification
BRT	RESTRAINT, PATIENT, CONDUCTIVE	CLASS I	80-GENERAL H

3. Repeat steps 1 and 2 to continue to add product codes.

OR

- If you do not know the three-letter code, see the instructions below to search for the code.

OR

- Click **OK** to return to the multiple product codes question.



Search Multiple Codes by Keyword


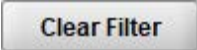
To search for multiple three-letter codes by keyword, follow the instructions below:

Action

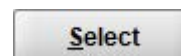
Graphic

1. Enter a keyword in **Product Code Name** to search the database. You will be provided a list of product codes from which to choose in the **Product Codes matching the specified filter criteria** portion of the dialog box.

Subsection 4.2.6: Question Types – Product Codes

2. To further refine your search, if desired:
 - Click the **Device Class** drop-down list and make a selection.
 - Click the **Classification Panel** drop-down list and make a selection.
 - Click the **Select Item** icon () next to the Identifier (under C.F.R. Selection) and make a selection.
 - Click  to remove entries and start the search over again.
-

3. Click to highlight the best match to your product/device, and click **Select**. The product/device appears in **Product Codes currently selected**.
-



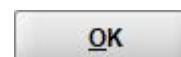
4. Repeat steps 1 and 2 to continue to add product codes.

OR

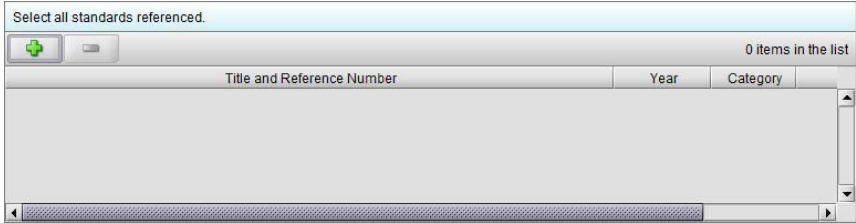
Click **Delete** to remove a product code from the selection.



5. Click **OK** to return to the multiple product codes question, which shows your selections.
-



Subsection 4.2.7: Question Types – Standards

Standards	<p>This question type allows you to select a standard for your submission from the list of recognized standards. Below is an example of a standards question.</p> 
------------------	--

Add a Standard To add a standard, follow the instructions below:

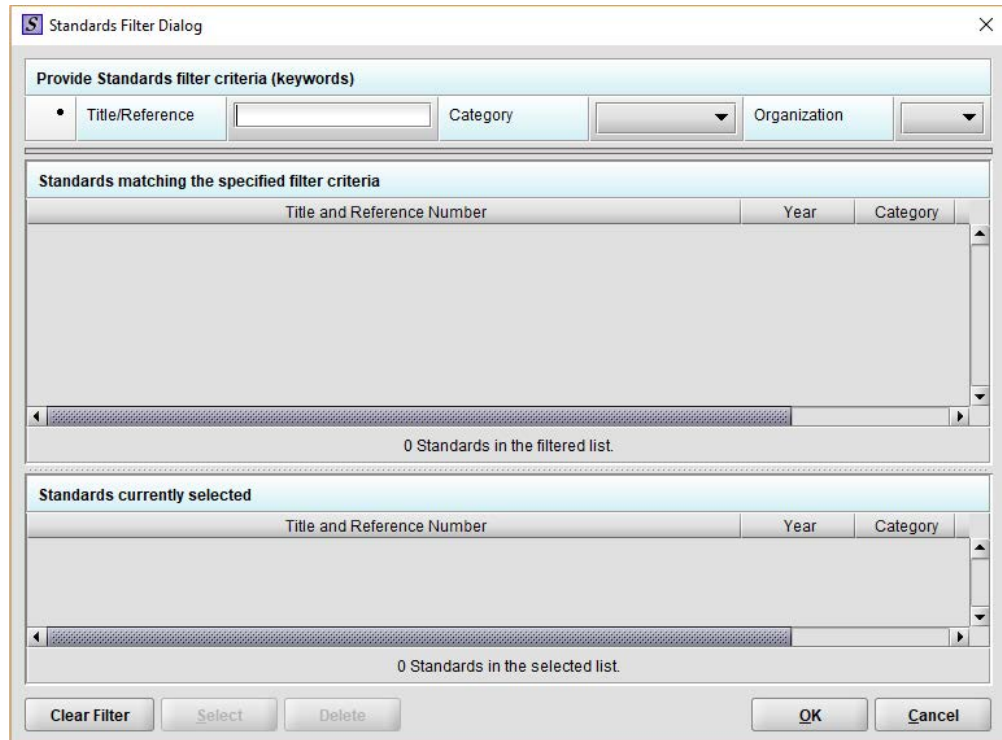
Action

Graphic

1. Click the **Add Standards** icon. You see the Standards Filter Dialog box (as shown below).




Standard Filter Dialog Box

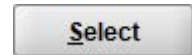


2. Enter title in **Title Reference** to search the database.

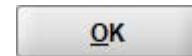
Subsection 4.2.7: Question Types – Standards

3. To further refine your search, if desired:
- Click the **Category** drop-down list and make a selection.
 - Click the **Organization** drop-down list and make a selection.
 - Click  to remove entries and start the search over again.
-

4. Click to highlight the best match to your product/device, and click **Select**. The standard appears in **Standards matching the specified filter criteria**.



5. When you are finished adding standards, click **OK**. You return to the standards question.



Subsection 4.2.8: Question Types – Sections as Tables

Sections as Tables with a Tabbed View

Entire sections may appear as a table. This is referred to as a tabular view, follow the instructions below:

List View

The tabbed view format is indicated by a row of icons for add icon, delete icon, delete all icon, buttons for List, Detail, and Info buttons, and left right arrows. **New**, **Delete**, **Delete All**, an up arrow, and a down arrow. Directly below this row of buttons is the actual table (as shown below).

Status Change	Manufacturer	Contract Manufacturer	Contract Sterilizer	Repackager/Relabeler
Yes	No	Yes	Yes	
No	No	No	Yes	Yes

You also see a **List** and **Details** tabs. Click the **New** button to add an item to the table. You see a screen containing questions for you to answer. An example is shown below.

Details View

Details of selected site

Status Change:

Site Operation:

- Manufacturer:
- Contract Manufacturer:
- Contract Sterilizer:
- Repackager/Relabeler:




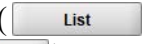
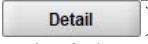



To see the items in the table, click **Details**. If you accidentally enter a blank into the table, (by clicking **New**, not responding to any questions, and then clicking **Details**), you will see a line of colored blank spaces. Select the line of colored spaces and click the Delete button to remove the item from the table.

Subsection 4.3: Relationships Across Screens

Sections as Tables with a Panel View

List View

Similar to the tabbed view, in the panel view, entire sections may appear as a table, follow the instructions below:

This format is indicated by a row icons and buttons **Plus** icon (), **Delete** icon (), **Delete All** icon (), **List** button (), **Detail** button (), **Info** button (), **Left Arrow** (), and **Right Arrow** () for previous and next items (as shown below).

Screen: Product Listing

Product Listing

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique P
>	1	Copenhagen	TP2312311			
	2	Marlboro	TP1123144	se11223	xxa1123	Item/Catalog Number

The left and right arrows, as seen below, will allow you to select a specific row when you have multiple entries. You can be sure that the appropriate row is selected as the row will be highlighted in blue and there will be an arrow in the right hand column. Please note the Item number column as this will be discussed in the List and Detail tab below.

List View with arrows

Screen: Component Identification

Product: Copenhagen

>	Item	Component Type	Component Type, If Other	Component Name
>	1	Tobacco Filler		Component 1
	2	Tobacco Filler Additive		Component 2
	3	Filter		Copp 1

To switch between Products click on the product name to get display the list of products to select.

Product	Copenhagen
	Copenhagen
	Marlboro

You also see a **List** and **Details** tabs. Click the **Plus** icon to add an item to the table. You see a screen containing questions for you to answer. An example is shown below.

Sections as Tables with a Panel View

Subsection 4.3: Relationships Across Screens

Detail View

Screen: Product Listing

Product Listing

Item: 1

PRODUCT IDENTIFICATION

Tobacco Product Brand/Sub-brand Name or Other Commercial Name (e.g., Acme Lights 100's or Acme Reconstituted Tobacco #202):

FDA-Assigned Tracking Number (TP#####):

If this product is under review or has been authorized under a marketing pathway, enter the submission tracking number of the application (e.g., SE1234567):

Product Identification Number (At least one product identification number must be provided if needed to uniquely identify the product.):

Select the type of product identification number:

▶ If Other, please describe further:

Use of Product: Consumer Use

Is this tobacco product a co-package? Yes No

Product Category: Smokeless Tobacco Products

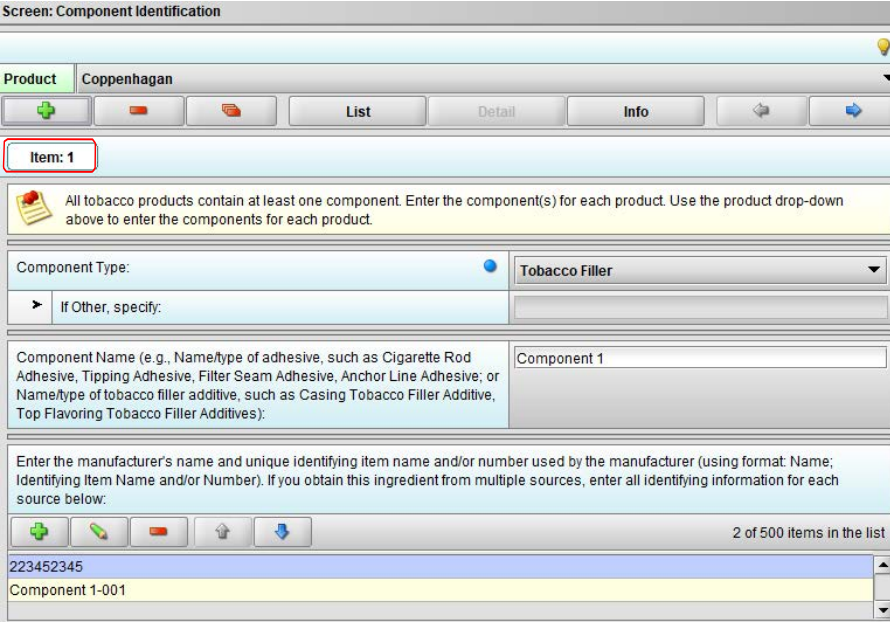
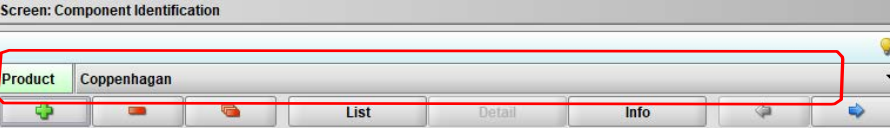
▶ If Other, please describe further:

Product Sub-Category:

▶ If Other, please describe further:

To see the items in the table, click **Details**. If you accidentally enter a blank into the table, (by clicking **Plus** icon, not responding to any questions, and then clicking **Details**), you will see a line of colored blank spaces. Select the line of colored spaces and click the **Delete** icon to remove the item from the table.

Subsection 4.3: Relationships Across Screens

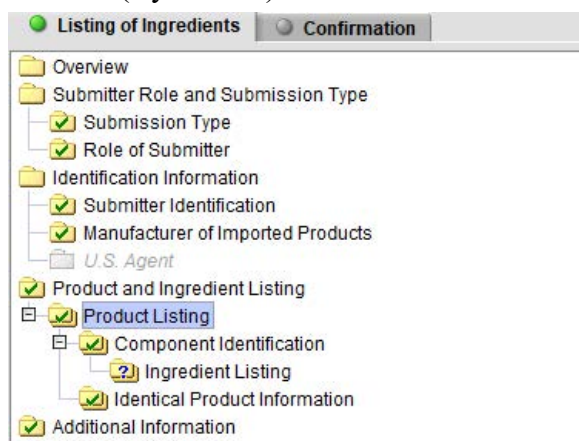
<p>Item Number</p>	<p>If you have added multiple entries, you will note that in the Detail or in the Add New view, the Item Number, highlighted below, will change based on the Item Number as seen in the List view above.</p> 
<p>Relationship Header</p>	<p>Some tabbed and/or panel screens may be linked together through a parent/child relationship, follow the instructions below:</p> <p>If this parent/child relationship exists, you will see a header bar on the child screens, as seen below, indicating which list item within the parent table you are currently entering data for. These child screens will be repeated for each list entry in the parent table, as necessary.</p> 

Relationships Across Parent and Child Screens

Subsection 4.3: Relationships Across Screens

Expert View Relationship

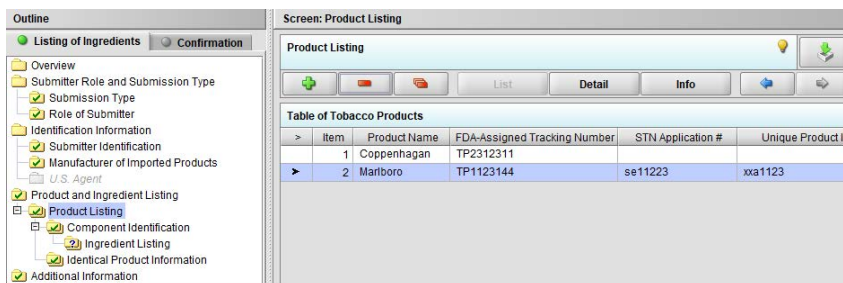
The parent/child relationship can also be seen when in expert view. As mentioned on page 36, the expert view allows the user to navigate through the form using an outline tree located on the left side of the screen. As seen below, the “Brand Logo and Registered Trademark” is a subfolder to the “List of Tobacco Products (By Brands) folder”. The subfolder is the child.



As you enter information into the parent and child screens, the user will use the List view and the headers to understand the relationship between the data. Changing the parent screens will cause the child screens to change. Please see below for an example.

In the expert view on the left, you see the parent folder named “Product and Ingredient Listing”, below, and the parent folder’s corresponding simple screen.

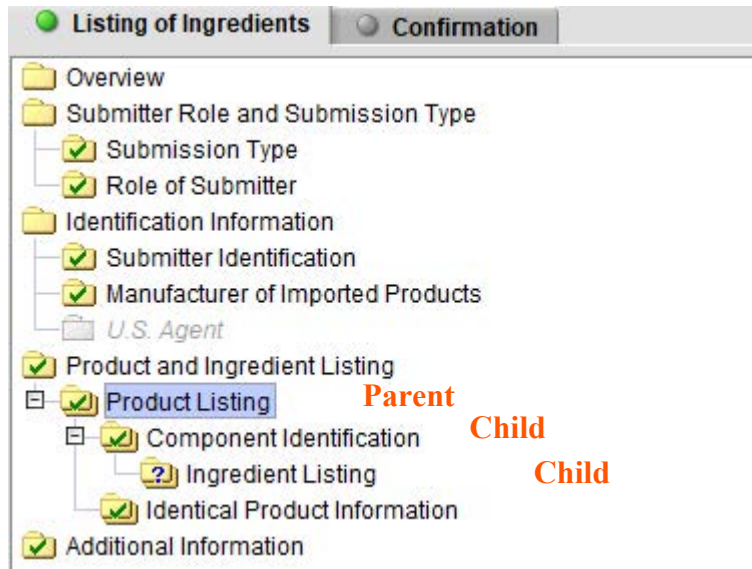
Relationship Example



In the right side of the screen seen above, the product category cigarette is selected. As you move through to the child folder “Sub-Brand Details (Packaging Level” and after entering the appropriate data, you will see the following information in the **List** view. Only the Parent in the Header is added to, to change that click on the parent name to see available parents and select the one you need.

Subsection 4.3: Relationships Across Screens

Once you enter information for one child, you can add more via the Plus icon from any of the Primary screens (Parent, Component, Ingredient in the above example




Subsection 4.4: Saving Submission Entries or Changes

Introduction

While moving through the submission, any changes made to question responses are automatically updated within memory (e.g., the user made a change to a question response, went to another section of the submission, and returned to see that the changes to the response were still in effect). If you have auto-save turned off in **Preferences**, these changes are only saved permanently when you select the **Save** option from the tool bar or **File** menu. Therefore, follow the same guidance that you would use when saving data in other software. In other words, whenever you have entered an amount of data that would be frustrating to have to re-enter, select the save option. For information on changing auto-save preferences, see page 15.

Note: The software will remind you to save if data has been changed and you are about to perform an operation that would result in losing your changes, such as opening another submission or exiting the application.

To save a submission, follow the instructions below:

Action	Graphic
1. Click File > Save .	
OR	
Click the Save icon on the tool bar. If you do not finish entering information into a submission in one session, you may return to it at another time. See Reopening an Existing Submission on page 33.	
2. If you wish to close the submission, click File > Close . The Intro Screen is then displayed.	

Subsection 4.5: Completing a Submission

Introduction To complete a submission, you must identify if any data is missing from your report (and then enter the required data), package the files for submission, find the necessary files on your computer, and copy the files onto a CD or transmit via the Electronic Submissions Gateway (ESG).

Missing Data You will only be able to package files for submission as long as no required data is missing from the submission. To determine if any data is missing, you will generate a Missing Data Report. To proceed, the desired submission should be open and displayed on your computer screen.

Note: All report outputs are generated as Rich Text and require an application capable of viewing Rich Text output, such as a WEB browser, the full version of Adobe Acrobat (not Acrobat Reader), or Microsoft Word.

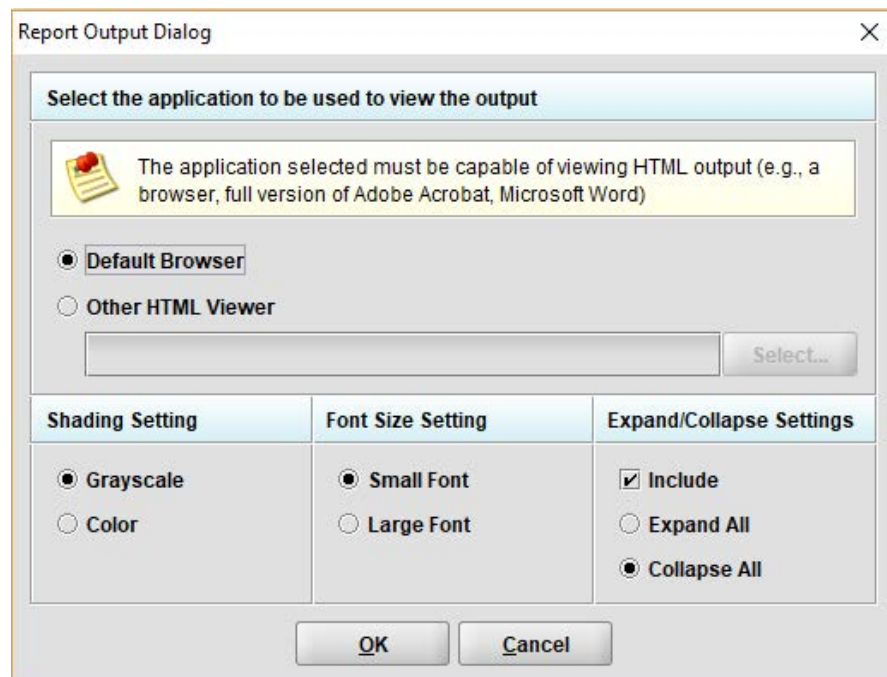
To determine if required data is missing from the submission, follow the instructions below:

Action

Graphic

1. From the menu bar, click **Output > Missing Data Report**. The Report Output Dialog box is displayed (as shown below).

Report Output Dialog Box



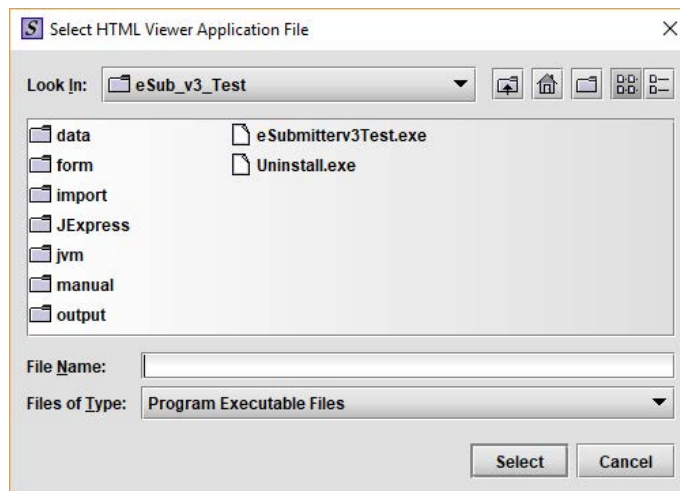
Subsection 4.5: Completing a Submission

2. On this dialog box:
 - Select the desired application to view the output in Rich Text:
 - Click the option button: **Default Browser** or **Other HTML Viewer** (The default setting is your Web Browser.)

⇒ If you selected **Other HTML Viewer**, the **Select** button becomes enabled. Click the **Select** button. You see the Select HTML Viewer Application File dialog box (as shown below).

Select

Select HTML Viewer Application File Dialog Box

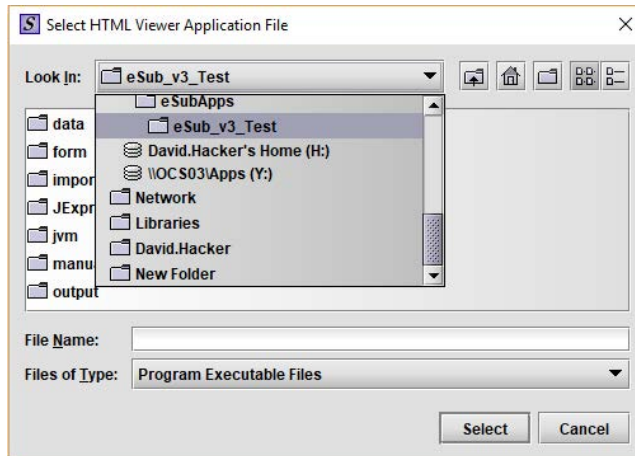


- Click in the **Look In** box to navigate to the **executable (.EXE)** of the application to view the HTML. For example, if you want to view the missing data output report in Word 2002, you would navigate using the following path:

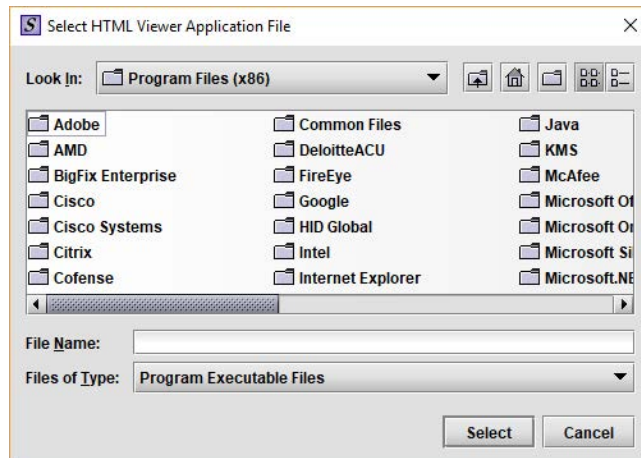
C: > Programs > Microsoft Office > Microsoft Office > Office 10> WINWORD.EXE

The following screens display an example for the navigation sequence to find Word 2002's executable (winword.exe):

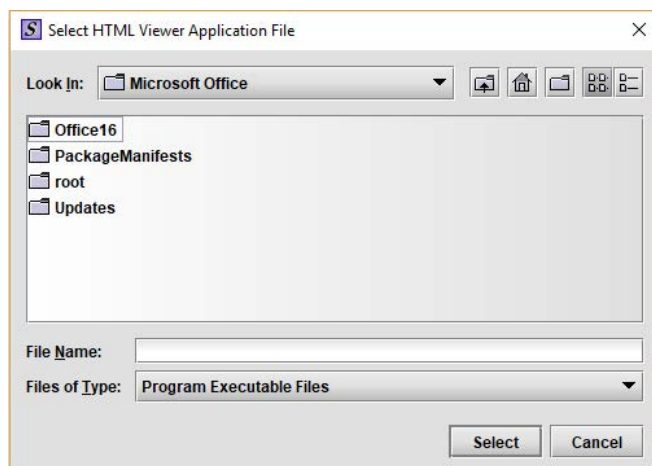
Subsection 4.5: Completing a Submission



Finding Word's Executable File (Navigation 1)

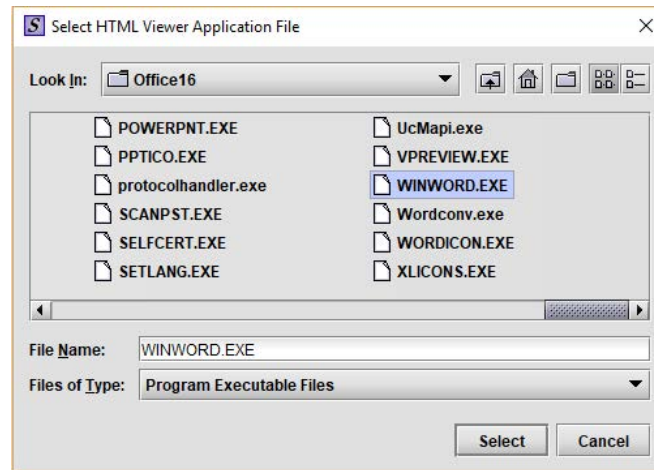


Finding Word's Executable File (Navigation 2)



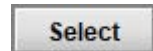
Subsection 4.5: Completing a Submission

Finding Word's Executable File (Navigation 3)

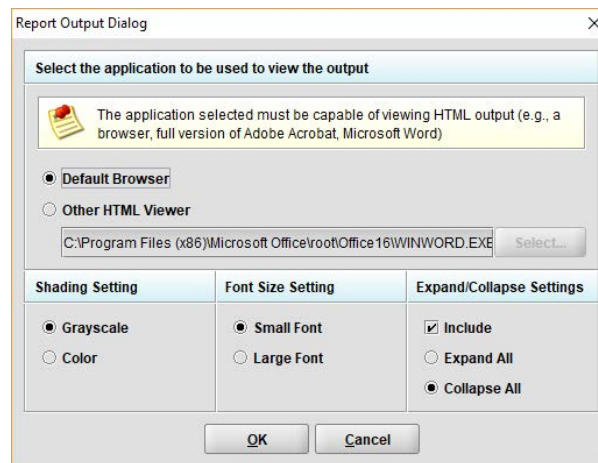


Finding Word's Executable File (Navigation 4)

4. Click **Select**. You return to the Report Output Dialog box with your selection showing (as shown below).

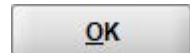


Report Output Dialog Box



Subsection 4.5: Completing a Submission

5. Select the desired shading of the report: click the radio button for either **Grayscale** or **Color**.
6. Select the desired font size: click the radio button for either **Small Font** or **Large Font** (which is approximately 10 pt).
7. When you are finished making selections, click **OK**. The eSubmitter software generates the report in Rich Text, which opens for viewing in the application that you selected. The missing data output report will either state that there is no data missing or identify the missing data that must be entered (as shown below) before the files are packaged for submission.

A screenshot of a web browser displaying a "Missing Data Report". The browser's address bar shows the file path "C:\Users\Public\Sub_Home\temp\missdata.html". The report is titled "Missing Data Report" and has a "Collapse All / Expand All" link. It is divided into several sections: "Section: Listing of Ingredients", "Submitter Identification", "Manufacturer of Imported Products", "U.S. Agent", and "Product Listing". Each section contains a list of fields with bullet points, indicating missing data. For example, under "Submitter Identification", the fields are: Country, Address - Line 1, City, Is the Authorized Representatives' Company Information the same as above?, Company Name, Country, Address - Line 1, City, State, Province, or Territory Name, and Zip or Postal Code. The "U.S. Agent" section lists: Address - Line 1, City, State, and Zip or Postal Code. The "Product Listing" section is currently empty. The browser's status bar at the bottom right shows "100%".

8. After you have verified that no data is missing from the submission, you are ready to package your files for submission.
-

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Packaging Submission Files

After completing the submission and verifying that there is no information missing, you are ready to package the files for submission. To proceed, the eSubmitter application should be open, and the finished submission displayed on your computer screen.

Package Files for Submission

To package files for submission, follow the instructions below.

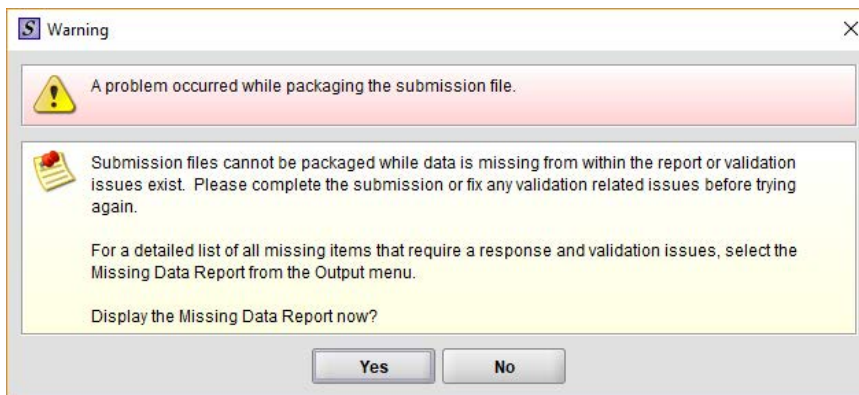
Action

Graphic

1. Click **Output > Package Files for Submission** from the menu bar.

2. If data is missing, see the warning (as shown below).

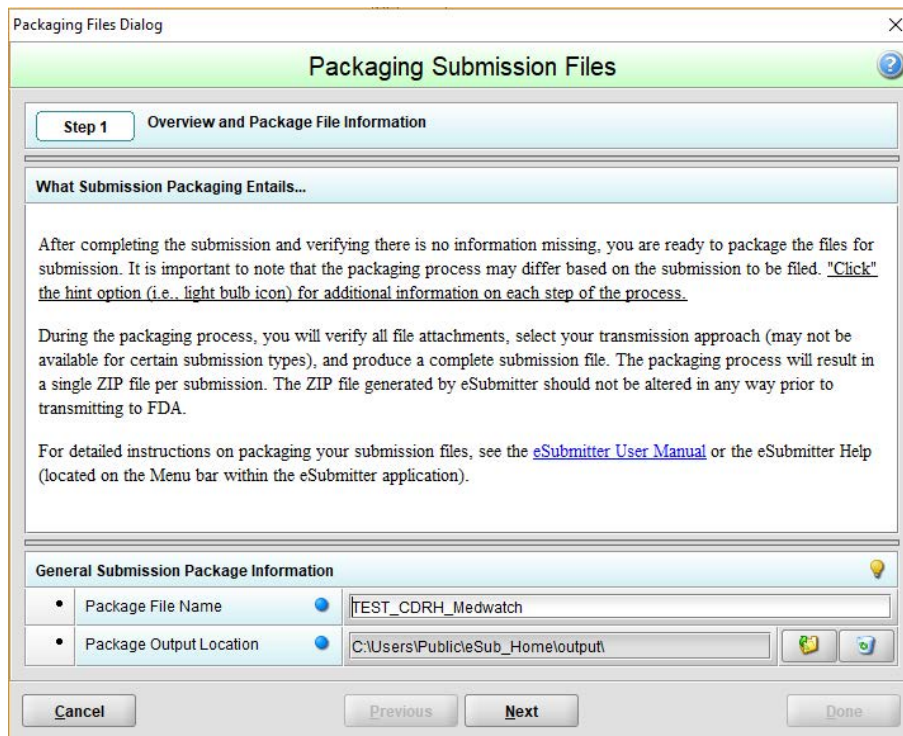
Warning



3. If the submission has all required data, the Packaging Files Dialog box is displayed (as shown below). Within the Packaging Files Dialog box you will be prompted to move through a series of steps detailed below.

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Packaging Files Dialog Box



Step 1: Overview and Package File Information

This section contains a brief overview of the packaging process. Follow the instructions below.

Action

Graphic

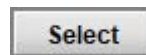
1. Specify the submission package file name.
 - The **Package File Name (.zip)** text box identifies the default zip file name for the submission. (eSubmitter automatically uses the submission name for the zip file.) Make a note of the name for the zip file.
-

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Action

Graphic

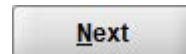
2. Specify the submission output location.
 - i. The **Package Output Location** identifies the file folder where the zip file is located. Make a note of the output location.
 - ii. To change the location click the file folder icon (as shown below), locate the desired location, and click **Select**.



General Submission Package Information

• Package File Name	TEST_CDRH_Medwatch
• Package Output Location	C:\Users\Public\Sub_Home\output

3. Click **Next** to proceed to Step 2: File Attachment Verification.



Step 2: File Attachment Verification

Packaging Files Dialog

Packaging Submission Files

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

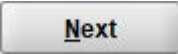
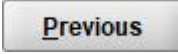
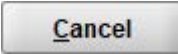
File Attachment List

File Name	File Title	Question Count	F
104 kb.pdf	104kb	1	02/12/2013
Y. 32 mb.PDF	2 mb	2	05/13/2015
a861.pdf	a1	1	07/12/2016
a11.pdf	a11	1	07/12/2016
a14.pdf	a14	1	07/12/2016
a15.pdf	a15	1	07/12/2016
a862.pdf	a2	1	07/12/2016
a4.pdf	a4	1	07/12/2016
a841.pdf	A41	1	07/12/2016
a842.pdf	A42	1	07/12/2016
a843.pdf	A43	1	07/12/2016
a5.pdf	a5	1	07/12/2016
a6.pdf	a6	1	07/12/2016
a863.pdf	a83	1	07/12/2016
a831.pdf	a831	1	07/12/2016
a832.pdf	a832	1	07/12/2016

Cancel Previous Next Done

This section lists all file attachments used in the submission.

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Action	Graphic
1. Check the list to ensure that all of the appropriate file attachments are listed (only files referenced in responses will be included). See above for an example.	
2. Check the question counts to confirm that the files are attached. <ul style="list-style-type: none"> ➤ NOTE: If a file appears to be missing from the list, go to the Submission File List within eSubmitter (File Menu > Tools > Submission File List). In the Master File List, ensure that each file is attached to a question. A zero in the Question Count column indicates that the file is not attached to a specific question and therefore will not be included in the packaged submission. 	
3. Check the file dates, size, and locations to ensure the correct versions of the files are provided.	
4. Click Next to proceed to Step 3 and continue packaging the submission.	
OR	
Click Previous to go back to Step 1 .	
OR	
Click Cancel and exit the Package File Dialog box.	

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Step 3: Transmission Approach, Submittal Letter, and Packaging

This section will differ based on the submission you are filing.

If a specific step listed below does not appear in the dialog box on your screen, this is because it does not apply. Please skip the instructions and move to the next step displayed on the Packaging Files Dialog box. Below is an example of what may appear in **Step 3**.

The screenshot shows a dialog box titled "Packaging Files Dialog" with a sub-header "Packaging Submission Files". The current step is "Step 3: Transmission Approach, Submittal Letter, Package Creation".

Select Transmission Approach

- Transmission Approach
 - Send through the mail on CD
 - Send electronically through the Gateway

Output Submittal Letter

- Submittal Letter
- Attach Signed Letter

Produce Submission Package

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

0%

Buttons at the bottom:

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Select Transition Approach (may or may not be applicable)

Choose the selected approach to send your submission to FDA.

- The first approach is the traditional CD and signed cover letter mailed to FDA. See below for an example.

The screenshot shows a dialog box titled "Select Transmission Approach". It contains a section labeled "Transmission Approach" with two radio button options: "Send through the mail on CD" (which is selected and highlighted with a red box) and "Send electronically through the Gateway".

- The second approach is only to be used when sending your submission through the FDA Electronic Submission Gateway (ESG).

NOTE: If you plan to send your submission through the ESG, you will need to register to use the ESG and set up an account. Please see [FDA ESG](#) for more information regarding the ESG. In addition, if the **Attach Signed Submittal Letter** is available, you must have the capability to scan your signed cover letter in the subsequent **Output Submittal Letter** step (see below).


The screenshot shows the same "Select Transmission Approach" dialog box, but now the "Send electronically through the Gateway" option is selected and highlighted with a red box.

Output Submittal Letter (may or may not be applicable)

Follow the instructions below for the Output Submittal Letter.

Action

Graphic

1. Click the  button, as shown below.

The screenshot shows a dialog box titled "Output Submittal Letter". It has two main sections: "Submittal Letter" and "Attach Signed Letter". The "Submittal Letter" section contains a button labeled "View/Print Submittal Letter...". The "Attach Signed Letter" section has a blue circular icon and a text input field. At the bottom right, there are icons for file operations (add, search, delete).

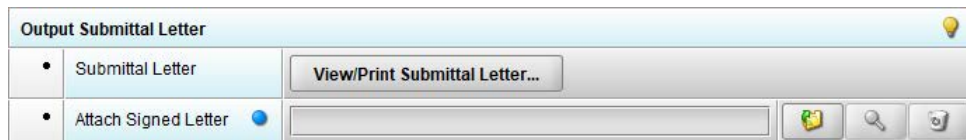
Subsection 4.6: Completing a Submission (Packaging Submission Files)

2.
 - a. Ensure that your submittal letter is accurate.
 - b. Print and sign the submittal letter.
 - c. Prepare to mail the submittal letter (for CD transmission approach)

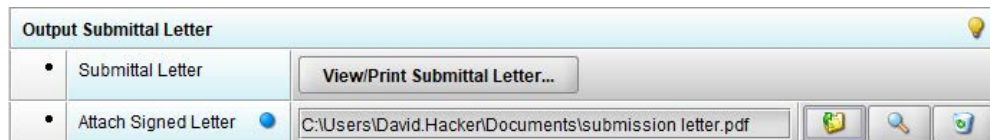
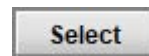
OR

- d. Scan the submittal letter (for Gateway transmission approach) and note the location where you store the file (you will need to navigate to this location in the next step).

-
3. Click on the **folder** icon (see below) to attach the signed submittal letter that has been scanned.
-



4. Once you have located the signed cover letter, click **Select** to attach the file to the packaging dialog box. The signed cover letter path should appear (as shown below).



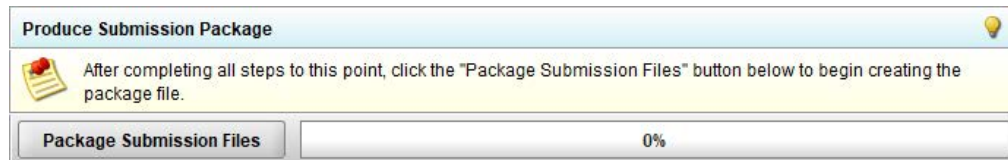
Produce Submission Package (Always available)

To produce a submission package, follow the instructions below.

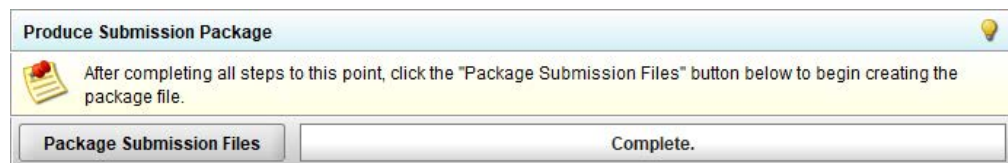
Subsection 4.6: Completing a Submission (Packaging Submission Files)

	Action	Graphic
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1. Click on **Package Submission Files** to initiate the packaging of the zip file (as shown below).

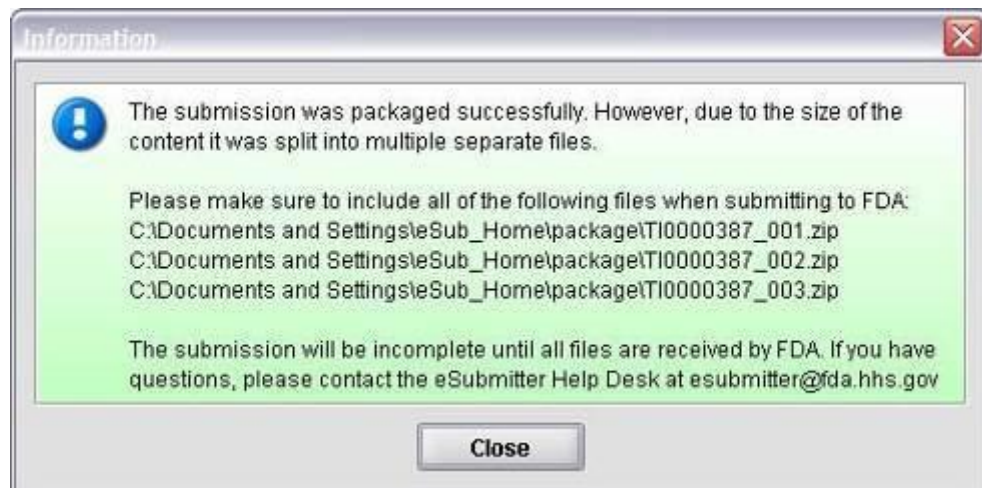


2. **NOTE:** Once the submission has packaged successfully, the status bar will indicate that the packaging is complete (as shown below).



Large Submission Size Confirmation Message

Very large submissions may be broken up into multiple packaged zip files. In that case, the following confirmation statement will be displayed:



Subsection 4.6: Completing a Submission (Packaging Submission Files)

3. Click **Next** to proceed to **Step 4** to view the transmission instructions related to your submission.

Next

Step 4: Transmit Submission Package

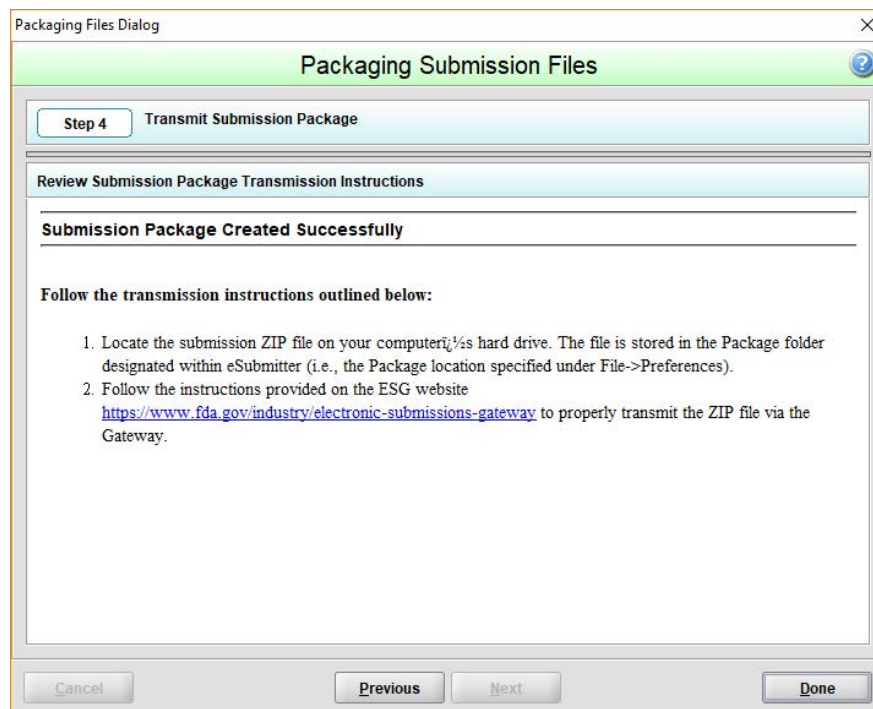
This section provides confirmation that the submission files have been successfully packaged. The submission is ready to be sent to FDA. Follow the instructions below.

Action

Graphic

1. Read the instructions provided. These instructions may vary depending on the approach selected in Step 3 (if the option was applicable). See below.
-

Transmit Submission Package



Subsection 4.6: Completing a Submission (Packaging Submission Files)

2. Click **Done** to close the Packaging Files Dialog box.



OR

- Click **Previous** to return to **Step 3**.



Printing, Locating, and Copying Files

The following instructions do not apply if you are transmitting your submission via the Electronic Submissions Gateway. Please see [FDA ESG](#) for Gateway transmission instructions. If you are transmitting your electronic submission on CD, follow the instructions below:

After packaging the files for submission, locate the packaged zip file on your computer and copy it onto a CD. In addition, you will need to mail the signed submittal letter (printed in **Step 3** of the eSubmitter Packaging Submission Files Process). **NOTE:** For an OIVD submission, the truth and accuracy statement is part of the letter.

Locate the Submission Files on the Computer's Hard Drive

To locate submission files on the computer's hard drive, follow the instructions below.

Action

1. Use Windows Explorer to navigate to the label for the computer's installed hard drive, e.g., **Local Disk (C:)**. For example, on a computer with Windows 2000:
 - Open Windows Explorer.
 - Double-click **My Computer** to display its contents.
 - Look for the label of the computer's installed hard drive. For example, **(C:)**.
 2. Double-click on the label for the hard drive to display its contents.
 3. Navigate to and double-click on the **Program Files** file folder to open.
-

Subsection 4.6: Completing a Submission (Packaging Submission Files)

Action

4. Navigate to and double-click on the **eSub** file folder to open.
 5. Double-click on the **output** file folder to open. The zip file that you created in Packaging Submission Files appears. **Do not modify the zip file after it is generated by eSubmitter.**
-

Subsection 4.6: Completing a Submission (Packaging Submission Files)

6. This step will differ based on the submission you are filing. Some programs accept a digital signature and submission via the Electronic Submissions Gateway and others require submission via CD-ROM and handwriting signatures. As of May 2015, the following is acceptable for each participating program:

CDER Program:

Generic Drug Facility Electronic Self-Identification: Digital signatures are not accepted at this time for GDUFA submissions. The CDER program only accepts submissions via the FDA Electronic Submissions Gateway.

CDRH Programs:

OIVD's 510(k): Digital signatures are not accepted at this time for OIVD 510(k) submissions. In the future, the digital signature will be available in conjunction with the FDA Electronic Submissions Gateway (ESG).

Radiological Health Reports and Correspondence: Digital signatures are accepted and required when utilizing the FDA ESG to submit reports and correspondence. See note below regarding the FDA ESG. RadHealth Submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CDRH in lieu of using the ESG. eMDR MedWatch 3500A Form: The eMDR program accepts digital signatures and utilizes the FDA ESG or transmission of the submission package. eMDR submissions may only be sent through the FDA Gateway.

Medical Device ISO 13485: Digital signatures are not accepted at this time for Medical Device ISO 13485 submissions. However, the CDRH program accepts submissions via the FDA Electronic Submissions Gateway, as well as sending in by CD.

eCopies: Digital signatures are not accepted at this time for eCopies submissions. eCopies submissions are accepted via CD and mailed to CDRH.

CBER Program:

OBRR BLA/BLS Submissions: Digital signatures are accepted and required for signing the necessary FDA OMB forms (Form 356h and Form 2567, when applicable). However, this CBER program does not accept submissions via the FDA Electronic Submissions Gateway at this time.

Subsection 4.6: Completing a Submission (Packaging Submission Files)

ICSR Adverse Event Reporting: Digital signatures are accepted and required when utilizing the FDA ESG for transmission of the submission package.

CTP Program:

Tobacco Product Ingredient Listing, Health Data Submissions, and other CTP submission types not listed: Digital signatures are accepted and required when utilizing the FDA ESG to submit ingredient listing and additional health data. Submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CTP in lieu of using the ESG.

Harmful and Potentially Harmful Constituents (HPHCs): Digital signatures are accepted and required when utilizing the FDA ESG to submit. HPHC submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CTP in lieu of using the ESG.

CVM Program:

ONADE: Digital signatures are accepted and required when utilizing the FDA ESG to submit eSubmitter electronic submissions to CVM.

OSC DER: Digital signatures are accepted and required when utilizing the FDA ESG to submit eSubmitter electronic submissions to CVM.

For additional information, please refer to the **eSubmitter Quick Guide PDF** in the “[Packaging and Transmission Guidelines for Participating eSubmitter Programs](#)” section.

Section 5: FDA Recommended PDF File Specifications

Introduction

Regulations in 21 CFR Part 11 require that the Agency be able to generate from any document provided in electronic format an accurate and complete paper copy that is both legible ("human readable") and suitable for inspection, review, and copying. Therefore, documents submitted in electronic format should:

- Enable the user to easily view a clear and legible copy of the information
- Enable the user to print each document page by page, as it would have been provided in paper, maintaining fonts, special orientations, table formats, and page numbers
- Include a well-structured table of contents and allow the user to navigate easily through the submission
- Allow the user to copy text and images electronically into common word processing documents

To achieve the above goals, you should submit all electronic documents in Portable Document Format (PDF). PDF is an open, published format created by Adobe Systems Incorporated (<http://www.adobe.com>). You do not need to use a product from Adobe or from any specific company to produce your PDF documents. PDF has been accepted as a standard for providing documents in electronic format by the International Conference on Harmonization (ICH).

Recommended PDF File Specifications

The following recommendations will help you create PDF files with the appropriate specifications to ensure that we can review and archive the electronic file attachments.

Section 5: FDA Recommended PDF File Specifications

PDF Area	Recommended PDF Specification
Version	The PDF files must be compatible with Adobe Acrobat 5.0 or greater without the use of additional plug-ins other than those provide by Adobe as part of Acrobat. We should not need any additional software to read and navigate the PDF files. There are features in Adobe Acrobat 8.0 that cannot be supported. If you would like to submit Adobe Acrobat 8.0 files, please contact technical support at esubmitter@fda.hhs.gov to ensure you do not use a feature that is unsupported.
Plug Ins	It is acceptable to use plug-ins to assist in the creation of a submission. However, the review of the submission should not require the use of any plug-ins other than any provided by Adobe as part of Acrobat, and must be compatible with Adobe Acrobat 5.0 or greater.
Page Size and Margins	The print area for pages should fit on a sheet of paper that is 8.5 inches by 11 inches. You should allow a margin of at least 1.5 inch on the left margin and 1 inch on all other sides to avoid obscuring information if the pages are subsequently printed and bound.
Page Orientation	Pages should be properly oriented. For example, you should set the page orientation of landscape pages to landscape prior to saving the PDF document in final form to ensure correct page presentation. Landscape pages (including tables) should be oriented such that the header and footer of the document align with the right edge of the page.
Fonts	<p>PDF viewing software automatically substitutes a font to display text if the font used to create the text is unavailable on the reviewer’s computer. Font substitution can affect a document’s appearance and structure, and in some cases it can affect the information conveyed by a document. We cannot guarantee the availability of any one font. Therefore, you should embed all fonts you are using in the PDF files to ensure that those fonts will always be available to the reviewer. When embedding fonts, all characters for the font should be embedded (not just a subset of the fonts being used in the document). One problem associated with embedding fonts is that embedding requires additional computer storage space. Three techniques to help limit the storage space taken by embedding fonts:</p> <ul style="list-style-type: none"> • Limit the number of fonts used in each document • Use only True Type or Adobe Type 1 fonts • Avoid customized fonts. <p>Resizing a document because the contents are too small to read is inefficient.</p>

Section 5: FDA Recommended PDF File Specifications

	<p>We believe that Times New Roman, 12-point font, is adequate in size for reading narrative text. This is the preferred font. Although sometimes tempting for use in tables and charts, fonts smaller than 12-points should be avoided whenever possible. We recommend the use of a black font color.</p> <p>Blue font may be used for hypertext links. If a font color other than black is used, avoid light colors that do not print well on grayscale printers. It is advised that you test the color reproduction prior to submission by printing sample pages from the document using a grayscale printer.</p> <p>In addition to font colors, keep formatting simple in tables. When extracting a table from the PDF document, the use of light or white font color will not allow the transfer of text back into some word processing documents.</p>
Page Numbering	<p>If a submission includes more than one document, you need not provide pagination for the entire submission. Include page numbers only for individual documents.</p> <p>It is easier to navigate through an electronic document if the page numbers for the document and the PDF file are the same. To accomplish this, the initial page of the paper document should be numbered page 1.</p>
File Size	<p>An electronic submission can have one or multiple file attachments. There is not a limitation of the total size of the submission, but each file should be limited to 50MB in file size. There are several ways to compress file size, including but not limited to: performing Optical Character Recognition, reducing file size in Adobe and creating logical section breaks.</p> <p>If you have questions about file size, please contact technical support at esubmitter@fda.hhs.gov to ensure the file size is acceptable.</p>
Document Properties: Description Tab	<p>Document properties are used to search for individual documents and to identify the document when found. To modify document properties, from the tool bar navigate to File Document Properties.</p>
Document Properties: Initial View Tab	<p>In the Document Properties box, the Initial View tab can also be found. In the Document Options section, all PDF files should set the Show field as Bookmarks Panel and Page. If there are no bookmarks, set the initial view as Page only. Set the Page Layout and Magnification fields to default.</p>
Document Properties: Security	<p>PDF files are stored as original documents and will not be altered from their original form. Remove any security settings, read-only, or password protection used on the files. Files submitted with security settings will not be accepted.</p>

Section 5: FDA Recommended PDF File Specifications

Indexing PDF Documents	<p>Full text indexes are used to help find specific documents and/or to search for text within documents. When a document or group of documents is indexed, all words and numbers in the file and all information stored in the Document Information fields are stored in special index files that are functionally accessible using the search tools available in Acrobat.</p> <p>Portions of a document that are imaged are not indexed. Even if the document only contains images, the text in the Document Information fields of the file will be indexed. All PDF files should be full-text searchable prior to submitting to the FDA.</p>
Bookmarks and Hypertext Links	<p>Bookmarks and hyperlinks should be used to assist the reviewers in navigating through the content of the submission. If you used either bookmarks or hypertext links, consider the following:</p> <ul style="list-style-type: none">• Use meaningful bookmarks (e.g., the title of the section, name of a study, data set, or facility). This will aid the reviewer in locating information and navigating the submission.• Bookmark references can be created for the heading of a section, subsection or title of figures and tables within the document. In general, including a bookmark to the main table of contents for a submission or item is helpful. Make the bookmark hierarchy identical to the table of contents.• Use hyperlinks within the file. Hyperlinks are used to improve navigation through PDF documents and are encouraged. Hyperlinks can be designated by rectangles using thin lines or by blue text or you can use invisible rectangles for hypertext links in a table of contents to avoid obscuring text. Hyperlinks throughout the body of the document to supporting annotations, related sections, references, appendices, tables, or figures that are not located on the same page are helpful and improve navigation efficiency. When creating bookmarks and hyperlinks, the magnification setting should be set to Inherit Zoom so that the destination page displays at the same magnification level that the reviewer is using for the rest of the document. <p>Important Note: Hyperlinks <u>between</u> individual PDF document files are not currently supported and any absolute links that reference across files will not work.</p> <p>In general, for documents with a table of contents, provide bookmarks and</p>

Section 5: FDA Recommended PDF File Specifications

	<p>hypertext links for each item listed in the table of contents including all tables, figures, publications, other references, and appendices. These bookmarks and hypertext links are essential for the efficient navigation through documents.</p>
<p>Optical Character Recognition</p>	<p>PDF documents produced by scanning paper documents are usually inferior to those produced from an electronic source document such as MS Word. Scanned documents are more difficult to read and do not allow the reviewers to search or copy and paste text for editing. The use of scanned documents should be avoided if at all possible. If scanning cannot be avoided, the following is highly recommended:</p> <ul style="list-style-type: none"> • Perform optical character recognition (OCR) on all scanned documents so that the text is searchable • Check to see that the content has been correctly converted. <p>If the source document is only available on paper, it should be scanned at resolutions that will ensure the pages are legible both on the computer screen and when printed. At the same time, remember to limit the file size to be less than 50MB. We recommend scanning at a resolution of 300 dots per inch (dpi) to balance legibility and file size. We discourage the use of grayscale or color because of file size. After scanning, avoid re-sampling to a lower resolution.</p> <p>For files with images and photographs:</p> <p>Also, when creating PDF files containing images, you should not resample images. Re-sampling does not preserve all of the pixels in the original. For photographs, the image should be obtained with a resolution of 600 dpi. If black and white photos are submitted, consider 8-bit gray scale images. If color photos are submitted, consider 24-bit RGB Color Model images. A captured image should not be subjected to non-uniform scaling (i.e., sizing).</p> <p>Files with scanned images and photographs tend to be large in file size. Please do not exceed 50MB for a single file. Consider multiple files for these types of documents.</p> <p>Note: Scanned tables and graphs cannot be extracted easily if scanned. Most OCR programs will distort the data in tables and graphs. Convert MS Word documents to PDF, as this method usually retains the formatting.</p> <p>For a paper document with handwritten notes:</p> <p>Paper documents containing handwritten notes should be scanned at 300 dpi. These handwritten notes should be made in black ink for clarity.</p>

Section 5: FDA Recommended PDF File Specifications

	<p>If you have questions about creating electronic copies, please contact technical support at esubmitter@fda.hhs.gov to ensure that the format is acceptable prior to developing your submission.</p>
Naming PDF Files	<p>We are recommending names for folders and selected files in individual guidances for specific submission types. For uniformity, we hope that you use our specific naming conventions when they are provided. Reviewers are trained to look for these folders and files, and using the recommended names should help avoid misunderstandings, improve communication, and speed the review of a submission.</p> <p>File names should not contain more than 250 characters. Do not use punctuation, spaces, or other nonalphanumeric symbols in file names when naming the files for attachments. For example, do not use slashes (/), tildes (~), asterisks (*), periods (.), brackets [], single quotation marks (‘), double quotation marks (“) or parentheses (). Once the file is attached to a question, it can be selected as an attachment to other questions, if appropriate.</p> <p>The eSubmitter tool supports the following file types:</p> <ul style="list-style-type: none">• Portable Document Format Files (.pdf)• Excel Files (.xls, .csv)• SAS System XPORT Files (.xpt)• Media Files (.wmv, .avi)• Image Files (.gif, .tif, .jpg)• Extensible Markup Language Files (.xml, .dtd)• Archive/Compressed Files (.zip)• Standard Generalized Markup Language Files (.sgml)• MDL Molfiles Files (.mol) <p>However, based on the application or report you are submitting, the question(s) may have restrictions on which file types you are allowed to attach. For example, some questions may allow you to attach any of the file types supported by eSubmitter and some may only allow you to attach PDF and Excel files as the questions response or supporting documentation.</p>

Section 6: FDA User Support

Introduction

For technical assistance for the eSubmitter software, an email can be sent to esubmitter@fda.hhs.gov. In the email, please be sure to provide the company name and contact information where a response can be sent.

For CBER - OBRR regulatory questions, please contact:
CBER_eSubmitter_program@fda.hhs.gov or your Consumer Safety Officer

For CBER-ICSR questions, please contact:
CBERICRSUBMISSIONS@fda.hhs.gov.

For CDRH - eCopies

For eCopy technical questions, please contact: cdrhesub@fda.hhs.gov.

For eCopy regulatory questions, please contact: CDRH-eCopyinfo@fda.hhs.gov.

For CDRH - eMDR regulatory questions, please contact:
eMDR@fda.hhs.gov.

For CDRH - In Vitro Devices and Radiological Health For regulatory questions, contact the Division of Industry and Consumer Education (DICE at dice@cdrh.fda.gov).

For CRDH technical questions, please contact cdrhesub@fda.hhs.gov.
1-800-638-2041

For CTP - Guidances or the Tobacco Control Act questions, please contact
TobaccoIndustryQuestions@fda.hhs.gov. 1-877-CTP-1373

For CVM related technical support or general inquiries, please contact:
cvmesubmitter@fda.hhs.gov.