FDA eSubmitter

User Manual

Document Version 5.9

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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.

FDA eSubmitter

Table of Contents

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Section 1: Introduction

Contents

This section contains the following topics:

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 seven 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** provides information about the Output menu on the menu bar, which includes reports and forms.
- **Section 6** provides information regarding 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**.

<u>Note:</u> 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
1.	Use Windows Explorer to navigate to the location of the **eSub** file folder on the workstation.	
2.	Delete the **eSub** file folder by right-clicking and selecting Delete.	
3.	When the previous version has been uninstalled, you are ready to install the current version of the eSubmitter software. See the following procedure.	

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	
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:\Program Files\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 *Networking* on page 18.	

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\eSub\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:

Subsection 2.1: Starting the Software

Introduction

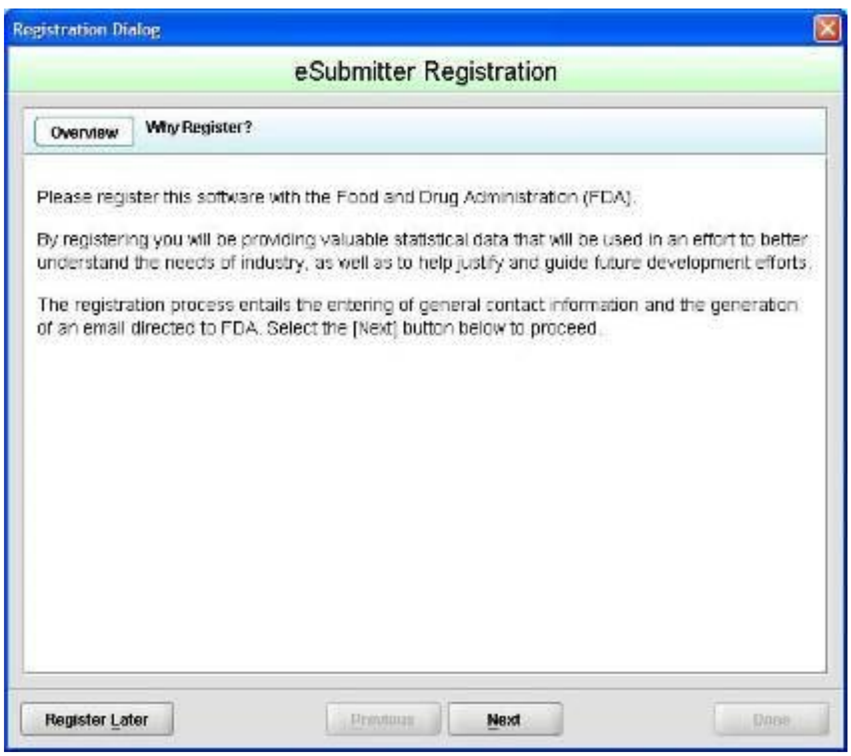
After you have successfully installed the eSubmitter software, you are ready to start up the application and create a new report.

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



	Action	Graphic
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.	 

Registration Dialog Box: Contact Information

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

Registration Dialog Box: Address Information

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

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.

Registration Dialog Box: Check Results

9. Select the button corresponding to either **Yes the Email was sent correctly** or **No there was a problem**.

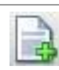
10. Click **Done** if the email was successful and to complete the registration process.

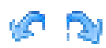
11. Next, you will see the *Intro Screen*, which is described in the subsequent section.

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.

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.

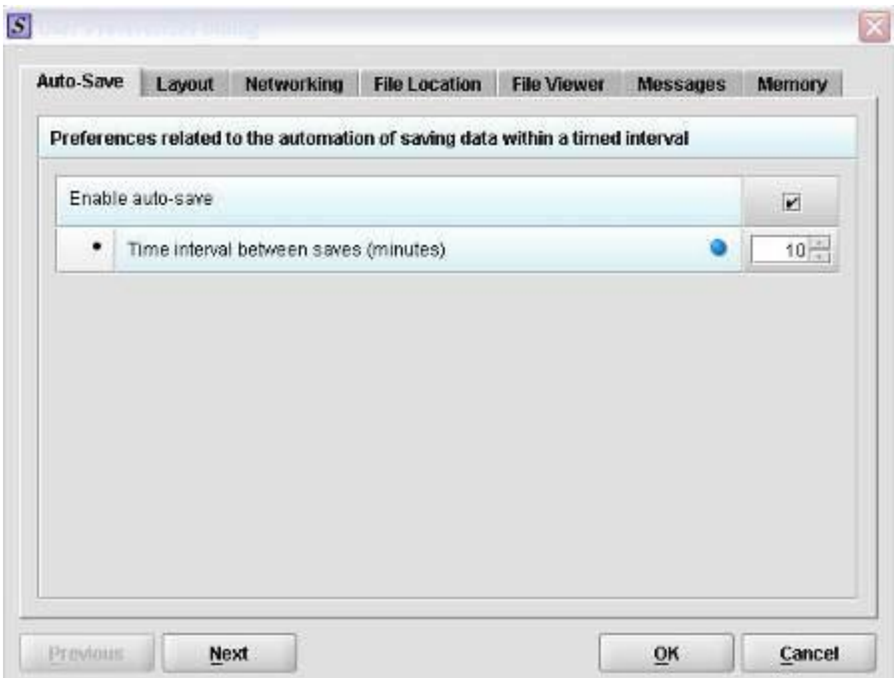
Subsection 2.2: Setting User Preferences

Introduction

eSubmitter allows you to set preferences for the following categories:

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

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).



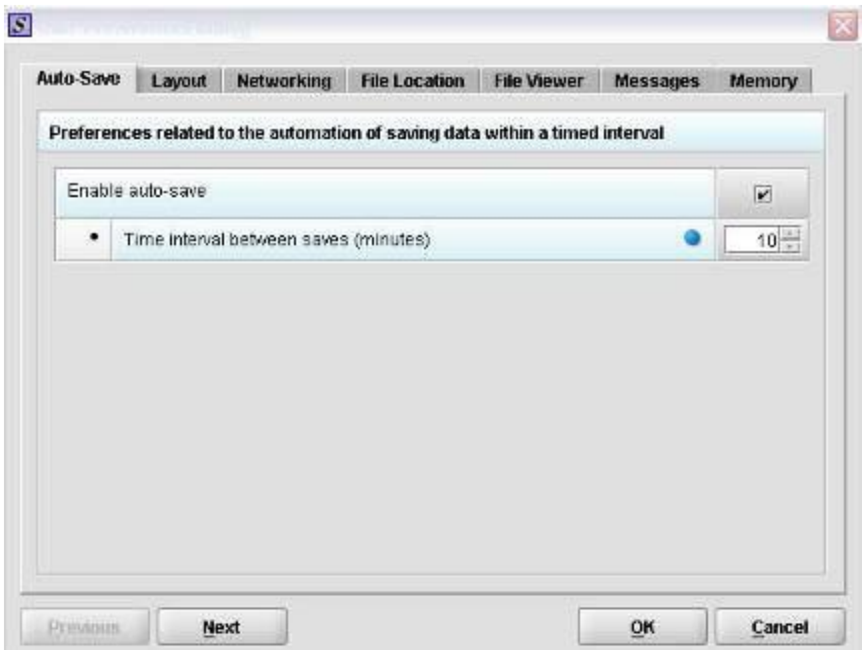
The subsections below will explain how to set preferences for each category.

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.

<u>Note:</u> 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.	

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

OR

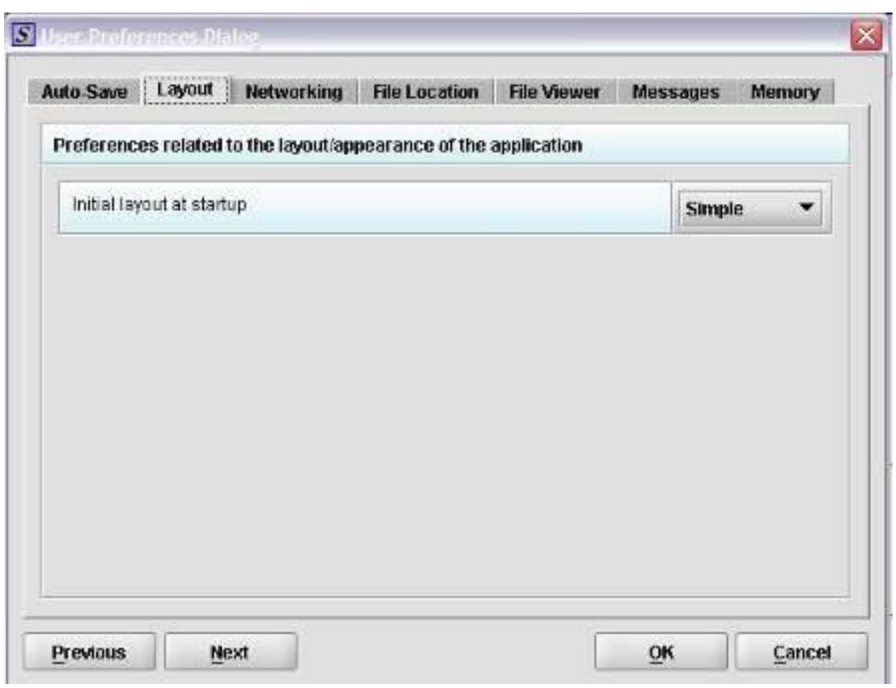
If you are finished and satisfied with your changes, click **OK** to close the *User Preferences Dialog* box with your changes saved.

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.	

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).	

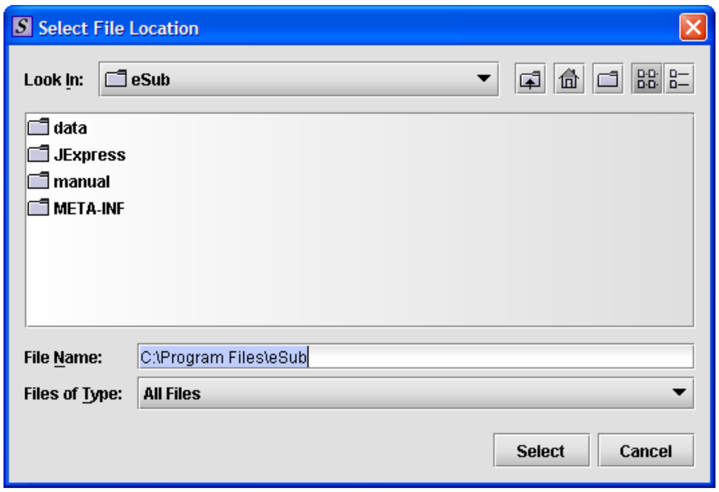
	Action	Graphic
2.	If you want to change the settings for networking, click **Next** or the **File Location** tab. See the description for **File Location** below.	
	OR	
	If you are finished and satisfied with your changes, click **OK** to close the *User Preferences Dialog* box with your changes saved.	
	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:

	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.	

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\.**

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

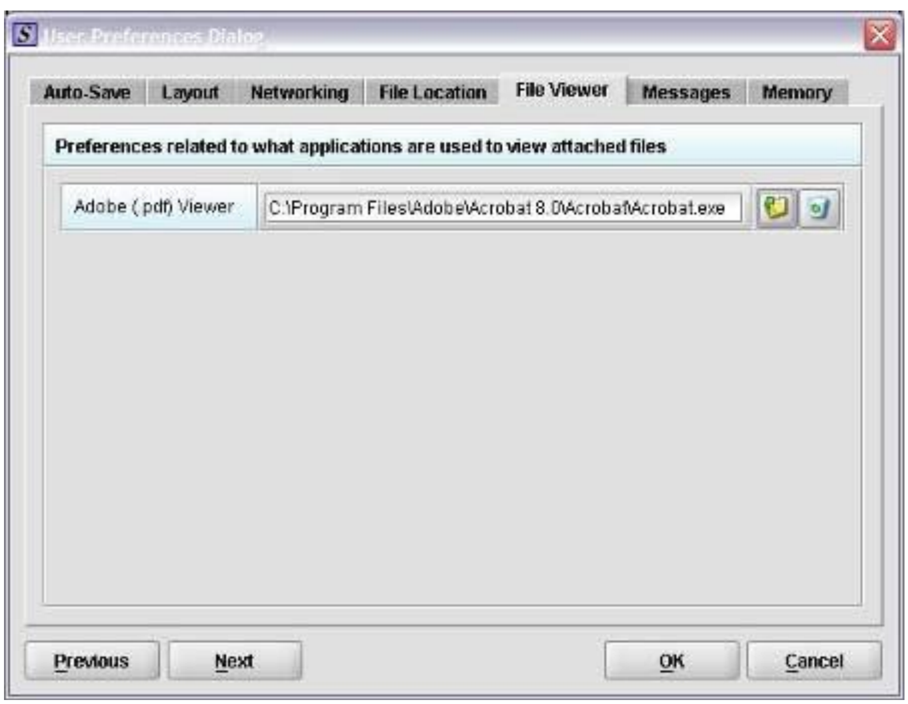
If you are finished and satisfied with your changes, click **OK** to close the *User Preferences Dialog* box with your changes saved.

OR

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

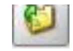
File Viewer

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.)

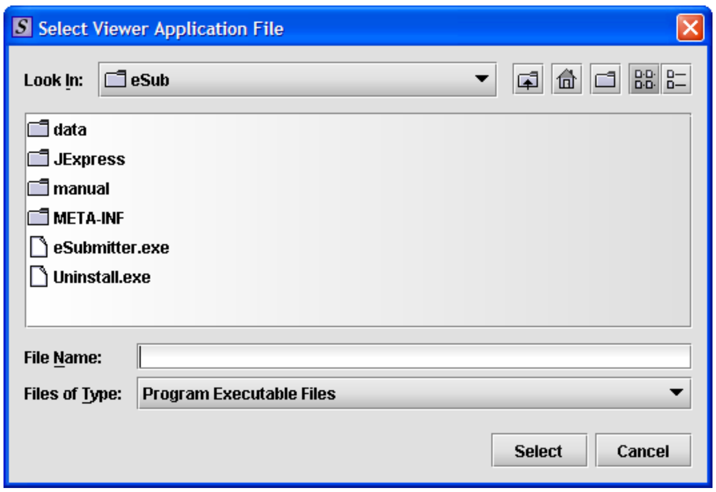


Follow these instructions to set up your PDF viewer:

Subsection 2.2: Setting User Preferences

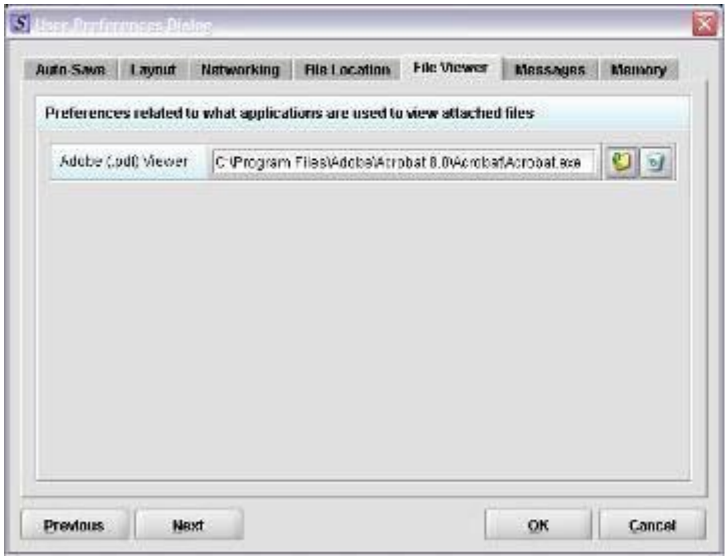
	Action	Graphic
1.	Click the **Select Location** icon to the right of the text box. The *Select Viewer Application File* box is displayed (as shown below).	

Select Viewer Application File Box



	Action	Graphic
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.	

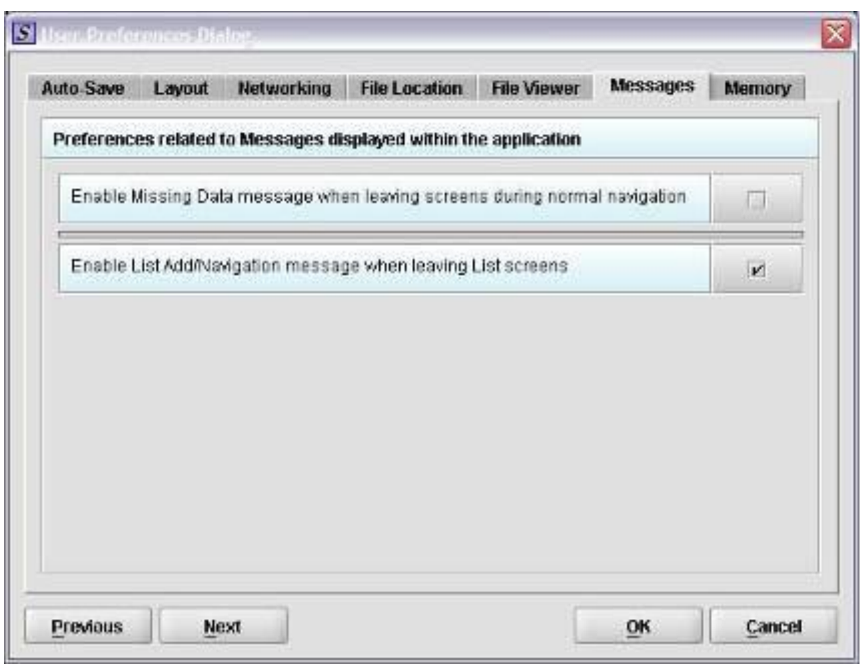
User Preferences Dialog Box



4. Click **OK**.

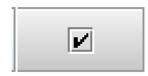
Messages

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.



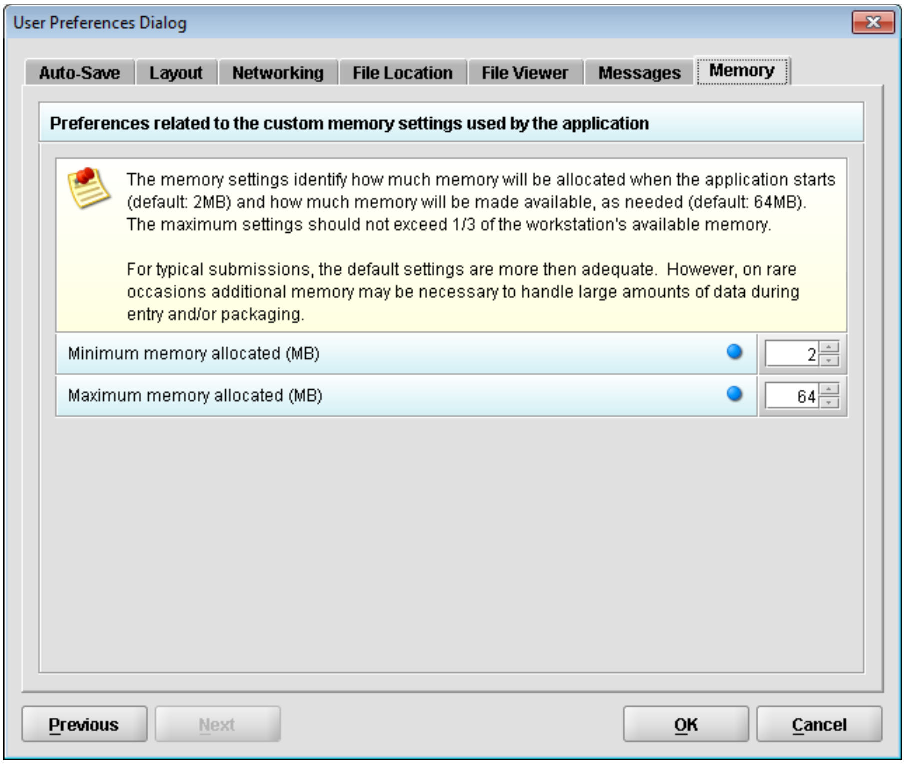
To enable these functions, do the following:

Subsection 2.2: Setting User Preferences

	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**.	

Memory

Allows you to identify how much memory will be allocated when the application starts (default: 2MB) and how much memory will be made available, as needed (default: 64MB).



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 2.3: Creating a New Submission

Introduction

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

<u>Note:</u> 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.

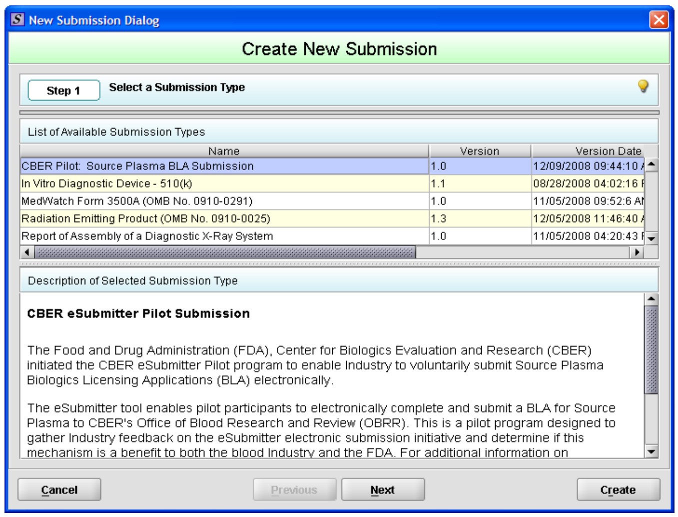
Create a New Submission

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

	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

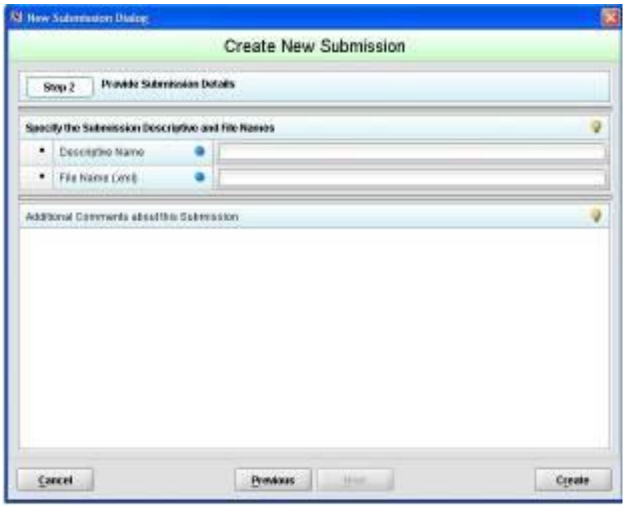
	Action	Graphic
2.	Click the **Create New Submission** button from the **Menu Options**. Or you may select **File > New** or, click the **New Report** icon on the Tool Bar. The *New Submission Dialog* box is displayed (as shown below).	 



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**.	

	Action	Graphic

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



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 ( ).

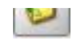
- **Provide additional comments…** – Enter any additional information about this report (Optional Entry).

	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.	

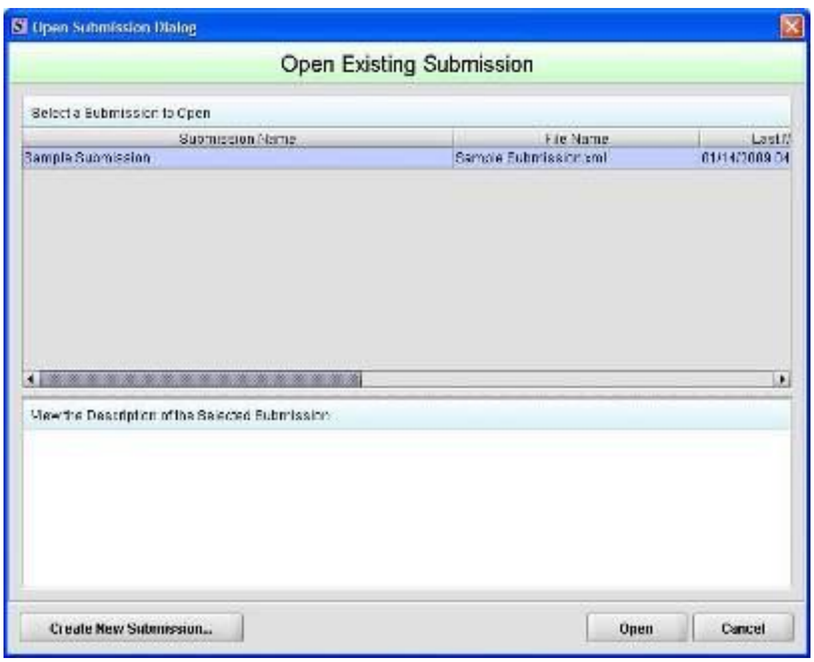
Subsection 2.4: Copy an Existing Submission to Create a New Submission

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).	

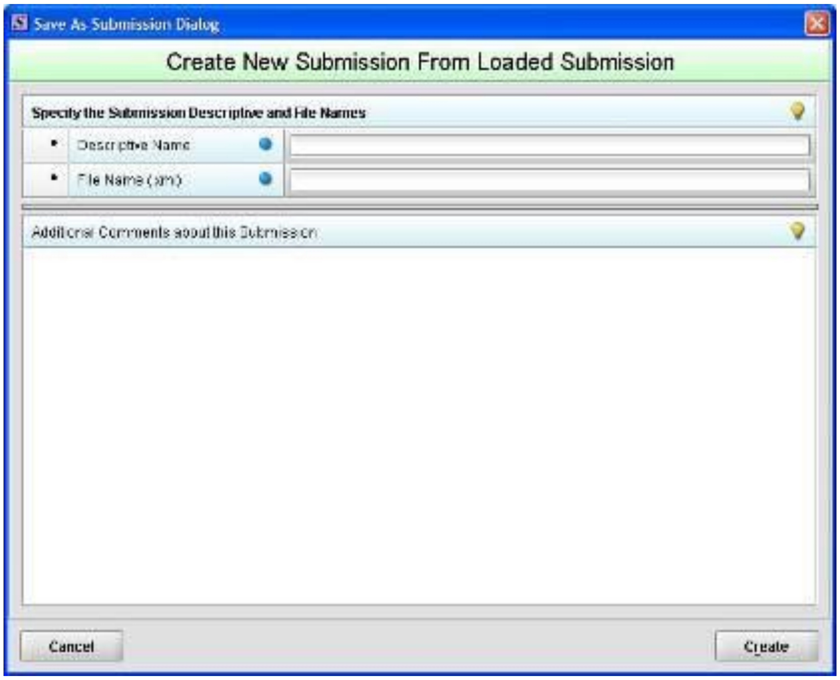
Open Report Data Dialog Box



	Action	Graphic
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 As Dialog* box is displayed (as shown below).	

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

Save Submission As Dialog Box



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).

5. When you are finished entering all information in the fields, click **Create**.

   The first screen of your new submission report is displayed.

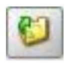
Subsection 2.4: Copy an Existing Submission to Create a New Submission

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.)
7. You are now ready to change the responses in this submission, go to *Entering Submission Information* on page 52.

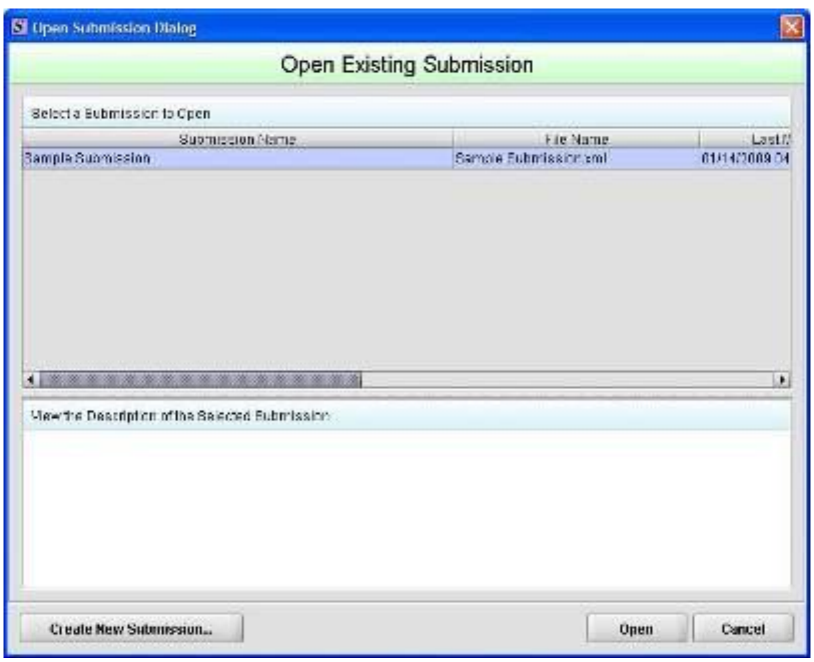
Subsection 2.5: Re-open an Existing Submission

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



	Action	Graphic
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:

Subsection 3.1: Application Window

Introduction

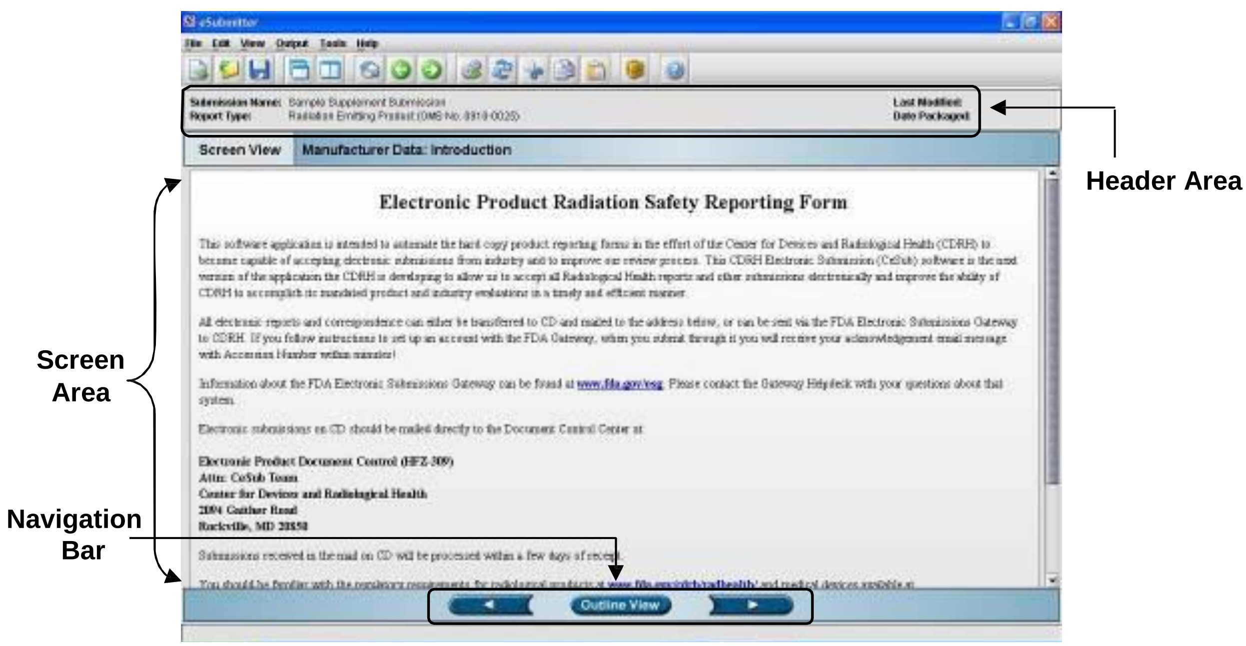
This section describes eSubmitter's Application Window and its different parts.

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):

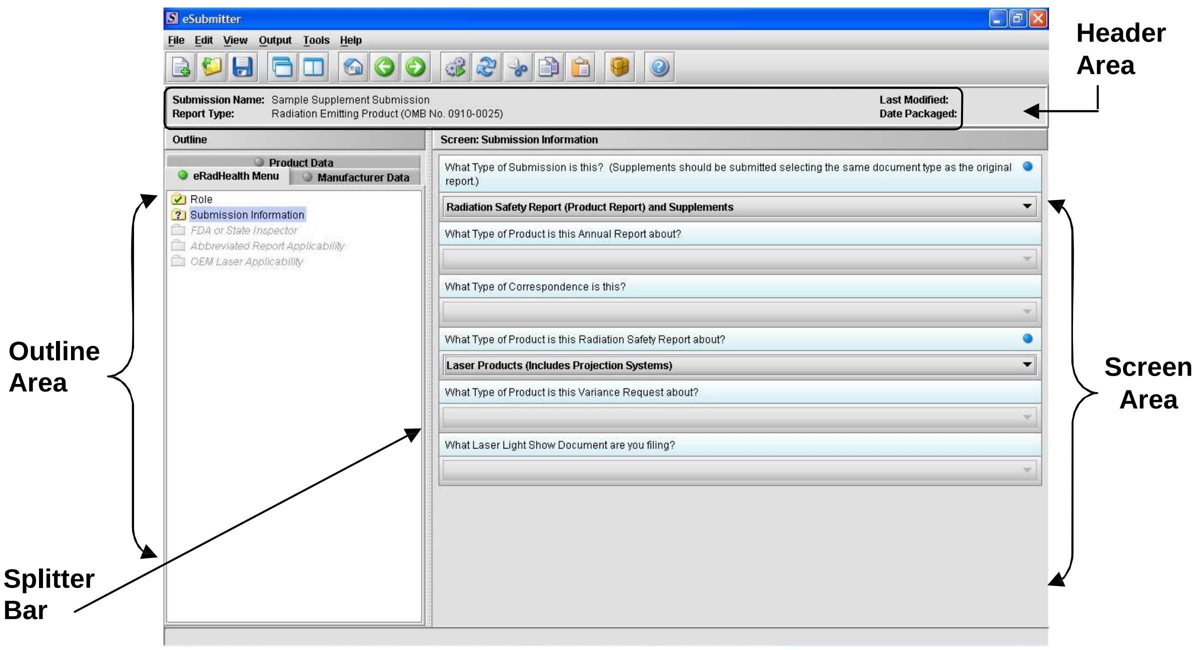
- **Header Area** (located at the top)
- **Outline Area** or **Screen Area** (located in the middle)
- **Navigation Bar** (located at the bottom), which allows forward and backward movement through the screens, as well as the ability to switch back and forth between the outline or screen view.



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)



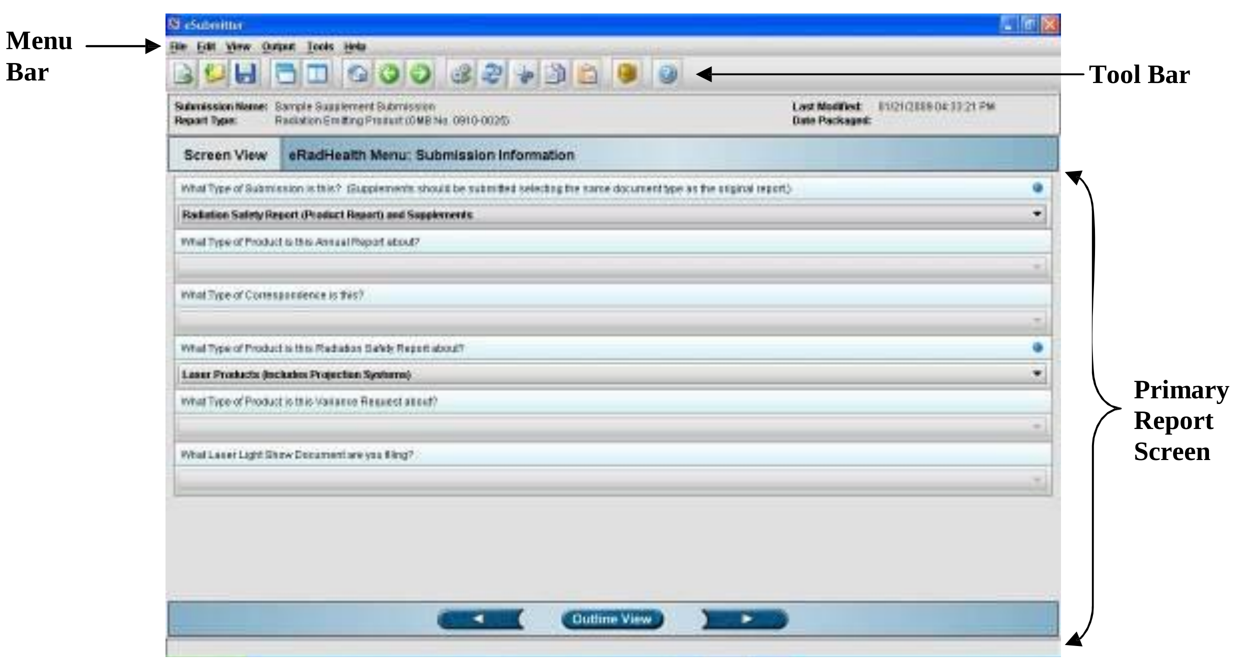
Subsection 3.1: Application Window

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:

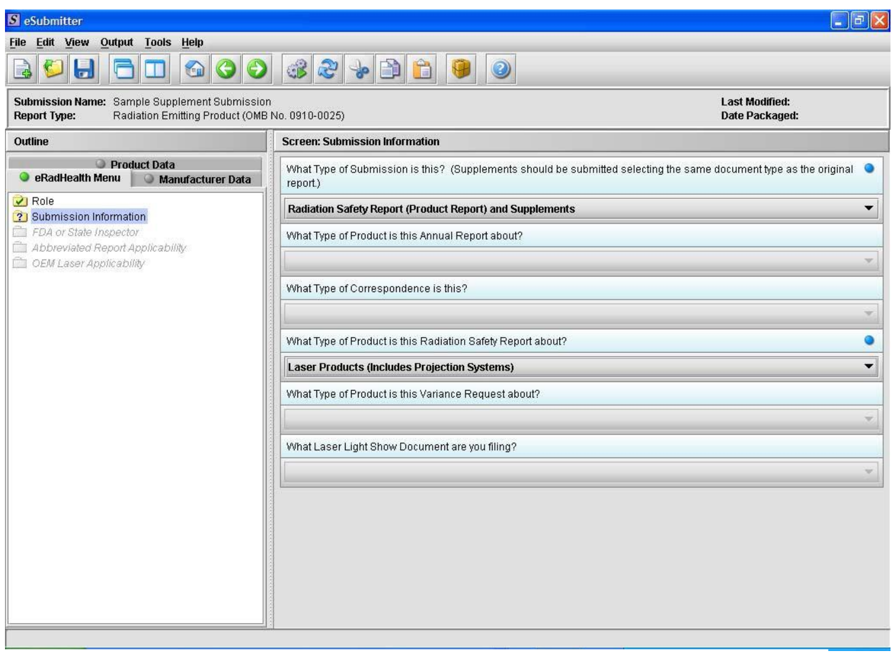
Header Area

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:

- **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.

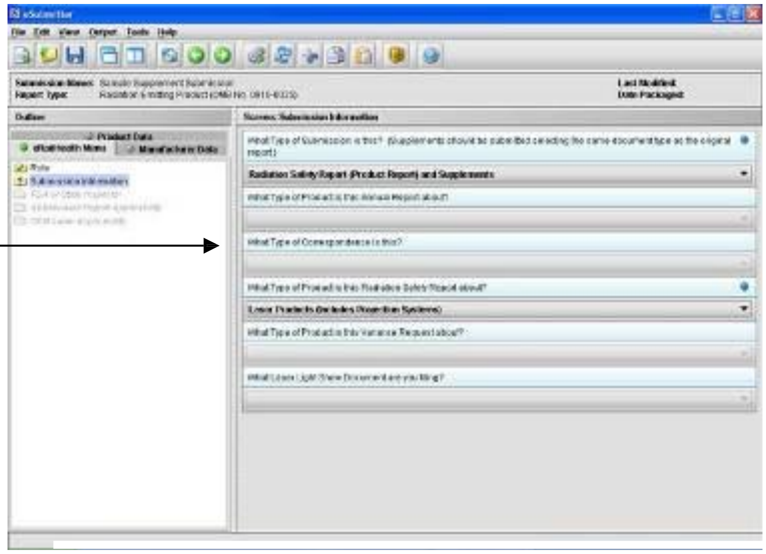
The presence of a scroll bar on the right-hand side of the screen area indicates that the screen extends below the view window. To scroll down to view questions and messages that are below the view window, press the downward scroll arrow.

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.

Splitter Bar



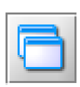
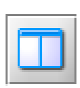
Subsection 3.2: Toolbar

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.

<u>Note:</u> 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.

	**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.

Output Menu Commands

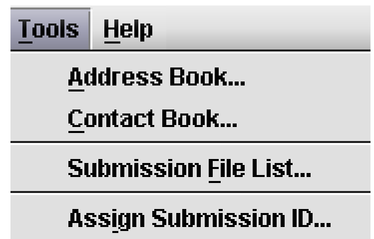
Each command on the Output menu is described below.

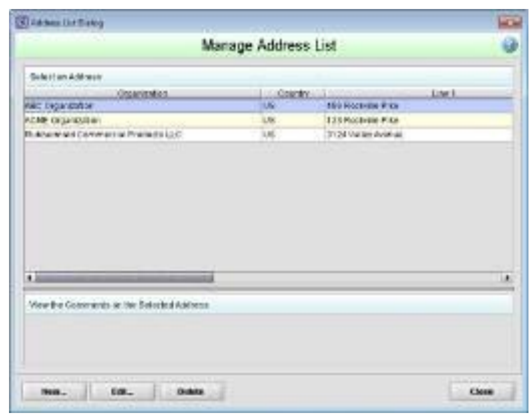
Tool	Function
Missing Data Report	Provides a list of required questions that you have not yet answered. The list is provided in Rich Text format. You can save the report file at any time. However, you will not be able to package a submission file to submit to FDA until there is no missing data. For complete information, see *Subsection 4.4: 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 4.4: Completing a Submission* on page 87.

Subsection 3.4: Menu Bar - Tools

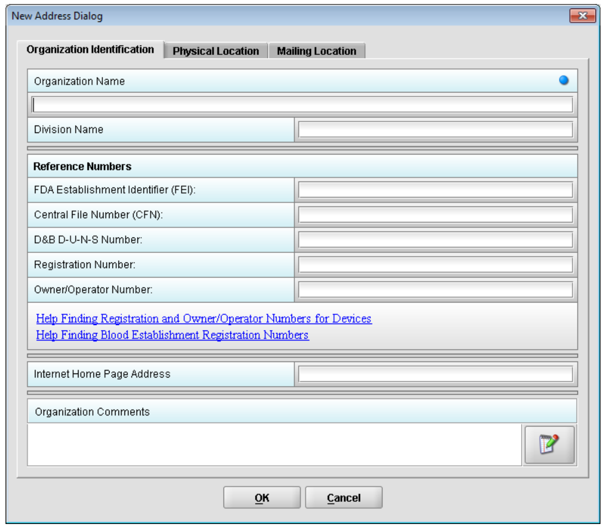
Introduction

Each command on the Tools Menu is described below:

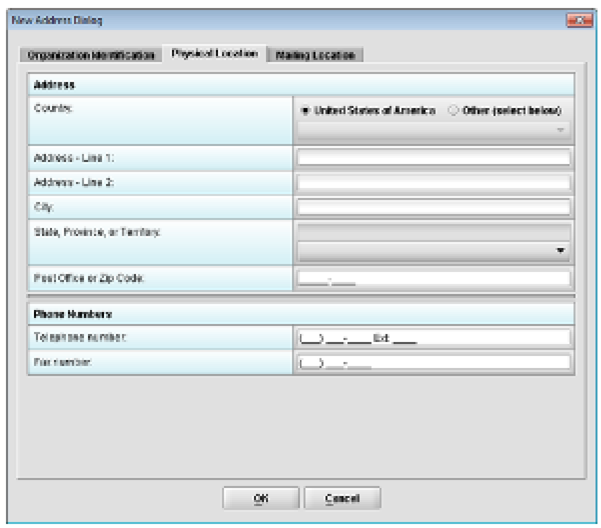


Tools	Function
Address Book	 Displays the *Address List Dialog* box, which provides the ability to maintain the addresses of the pertinent manufacturing and corporate facilities associated with your reports. You only need to enter each organization name and address once into the Address Book, then select 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. The *Address List Dialog* 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. The options (**New**, **Edit**, **Delete**, and **Close**) in this dialog box are described below:

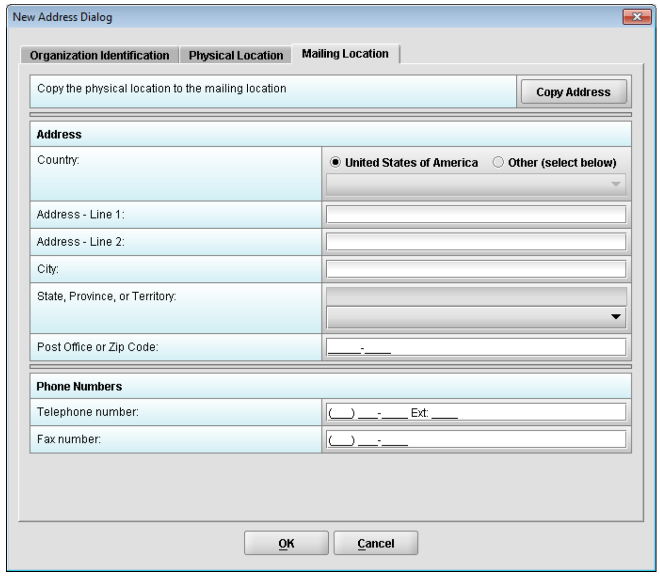
<table>
<tr>
<td>New</td>
<td>
Displays the New Address Dialog box, which allows a new organization to be created. Below is an example. Enter information in the fields to identify a particular organization.

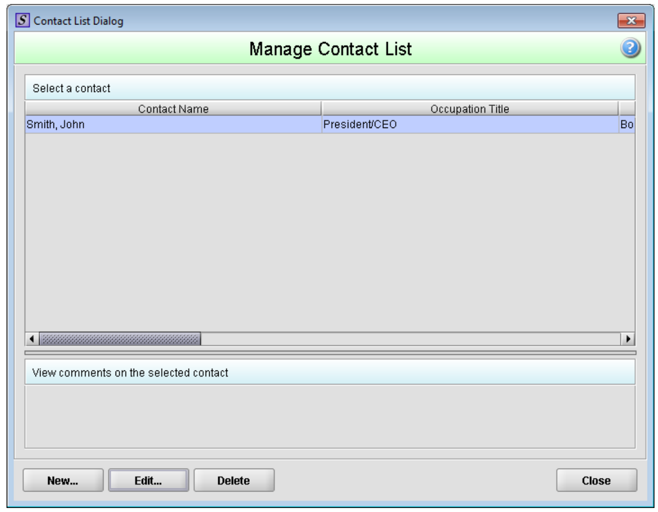


⇒Click the Physical Location tab to enter address information for where the organization is physically located. See below.

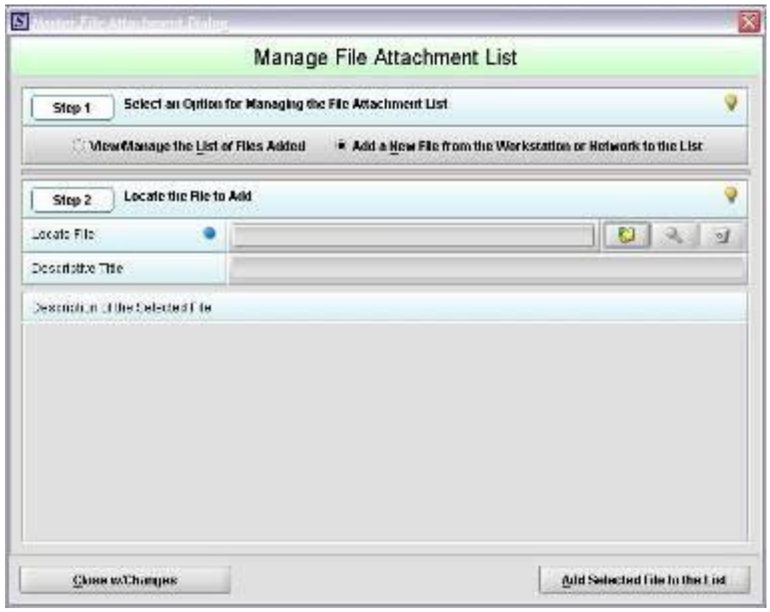


⇒Click the Mailing Location tab to enter address information for the mailing address of the organization.
</td>
</tr>
</table>

	 ⇒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 *Address List Dialog* box.
Edit	Displays the *Edit Address Dialog* box, which allows the selected establishment information to be changed. (You enter information in this dialog box in the same manner as the *New Establishment Dialog* box.)
Delete	Deletes the selected address from the list.
Close	Closes the dialog box.

Tools	Function
Contact Book	Displays the *Contact List Dialog* box, which allows the names and addresses of the pertinent people associated with the report to be maintained. You only need to enter each person's name and contact information once into the Contact Book, and then you can select the appropriate individual in response to each question. Existing addresses can be selected (from the Address Book) for each contact. The Contact Book will be retained and accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries.  The *Contact List Dialog* box contains a list of all the available contacts and a comments area for viewing the comments for each selected contact. In addition, if you scroll across the contact list, you will see fields containing basic identifier information about each contact. The options provided in this dialog box are described below:

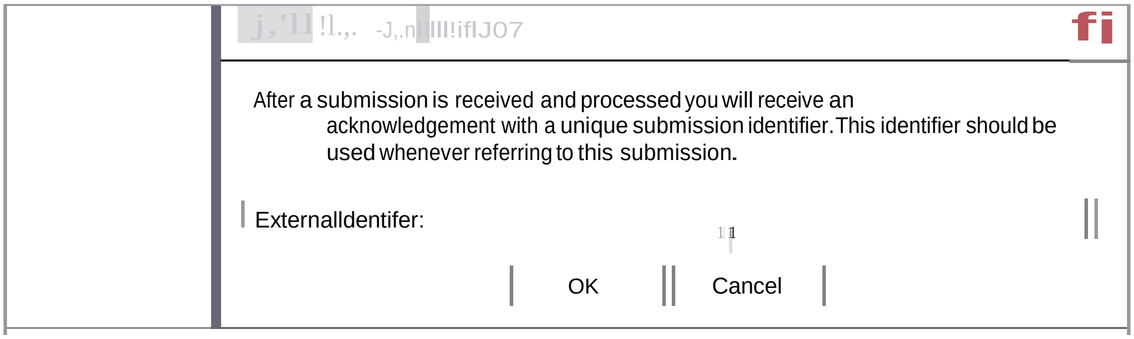
New	Displays the *New Contact Dialog* box, which allows a new contact to be created.
Edit	Displays the *Edit Contact Dialog* box, which allows the selected contact information to be changed.
Delete	Deletes the selected contact from the list.
Close	Closes the dialog box.

Tools	Function
Submission File List	Displays the *Master File Attachment Dialog* box, which allows you to manage the file information to be attached for use across questions in the submission.  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. **<u>Note:</u>** The file list is specific to the submission that is currently open, thus not retained nor accessible for future reports. The *Master File Attachment Dialog* 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: • 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 The options provided in the dialog box are described below:

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.

Tools	Function
Assign Submission ID	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. **To enter a Report ID:** ⇒ 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.


After a submission is received and processed you will receive an acknowledgement with a unique submission identifier. This identifier should be used whenever referring to this submission.
ExternalIdentifer:
OK
Cancel

Section 4: Preparing a Submission

Contents

This section contains the following topics:

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:

   - If you are in the simple layout, use the buttons on the navigation bar to advance to next/return to previous screen.

   - 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.

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

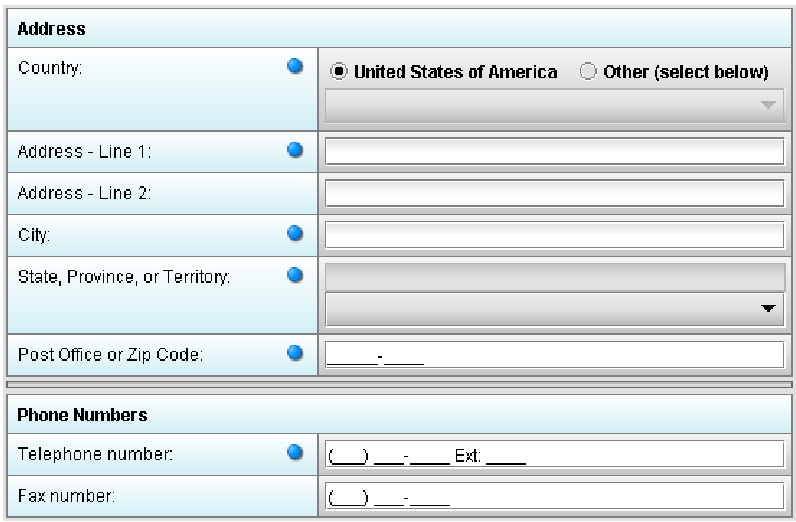
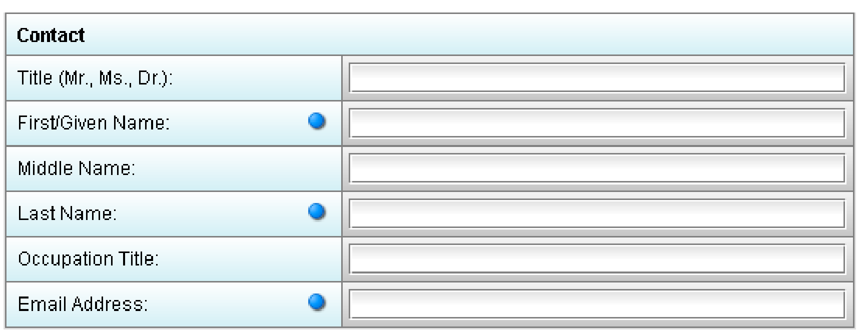
Question Types

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.

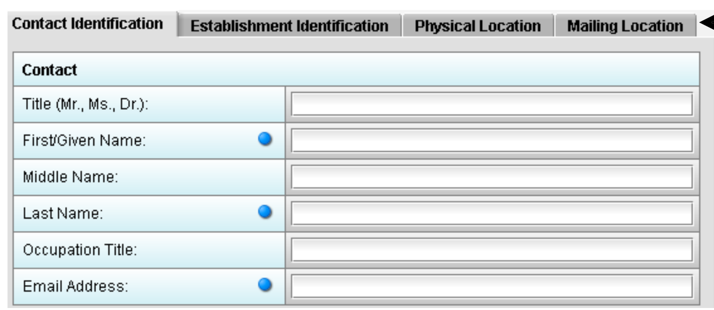
Subsection 4.2.1: Question Types – Address and Contact Information

Address	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. 
Contact (Simple)	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). 
Contact (Multi-Part)	This question type contains multiple sections that you need to complete (indicated by the tabs: Contact Information, Establishment Identification, Physical Location, and Mailing

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.



Tabs

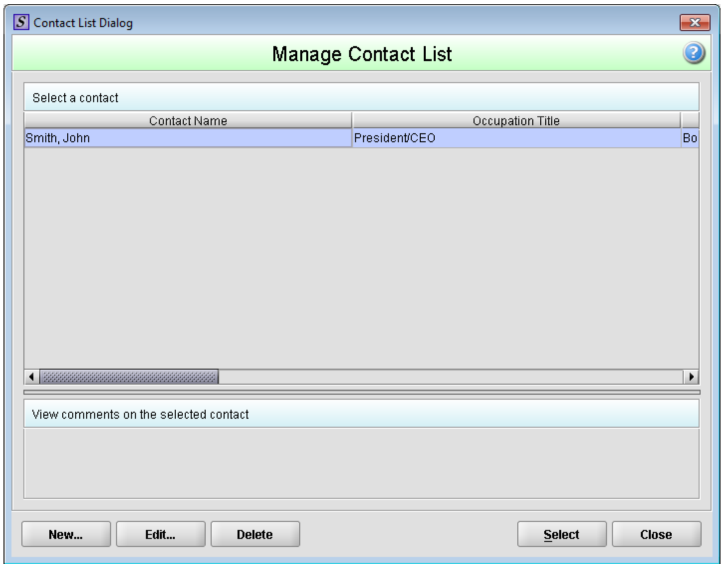
Copy Information from Contact Book into Question

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.

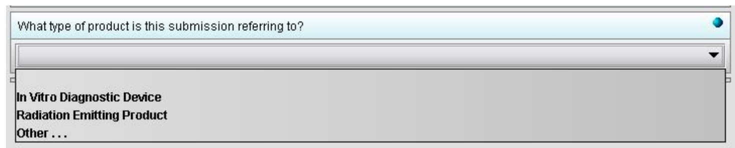
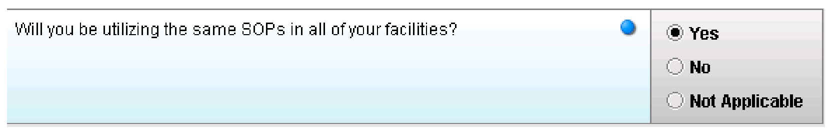
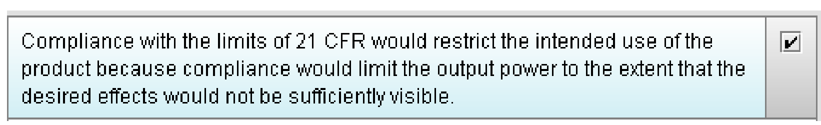
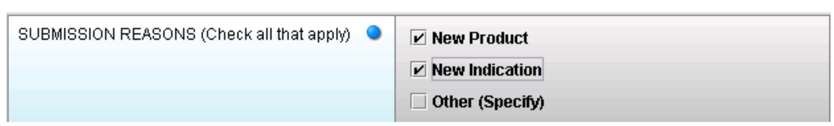
3. Click **Select**. The contact information is automatically populated in the different entry areas (within each applicable tab).

4. If the information is not exactly the same, you can edit the information in the question fields after you have copied it.

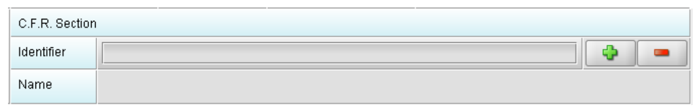
5. To see the other information, click on the desired tab. If you copied the contact information from the Contact Book, the information for these tabs will be completed as well.

6. For more information about Contact Books, see page 54.

Subsection 4.2.2: Question Types – Option Lists

Drop-Down Menu	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. 
Radio Button	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. 
Check Box	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. 
Check Box Group	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. 
Date	This question type requires that you type in a date, using mm/dd/yyyy format as a response. See the example below. 
Date Range	This question type requires that you type in a date range, using mm/dd/yyyy format as a response. See the example below.

Subsection 4.2.2: Question Types – Option Lists

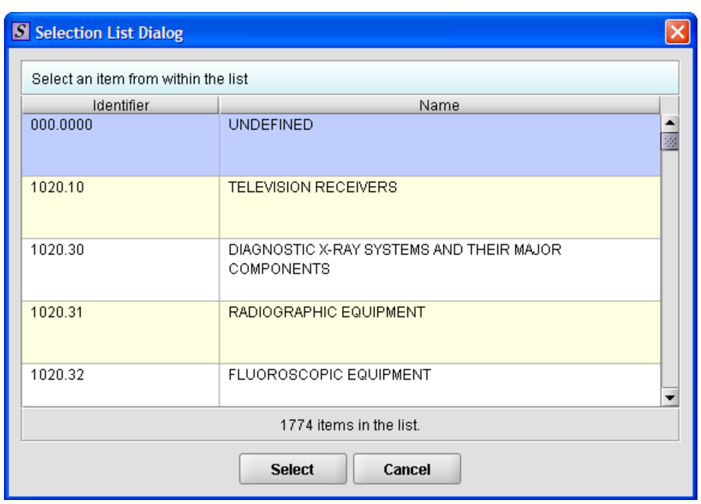
	
Numeric Spinner	This question type allows you to use the up and down arrows to select a number. Alternatively, you may enter a number directly into the field. See the example below. 
List Item	This question type allows you to select an item from a list of options. Below is an example of a list item question. 

Access the List of Available Options

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

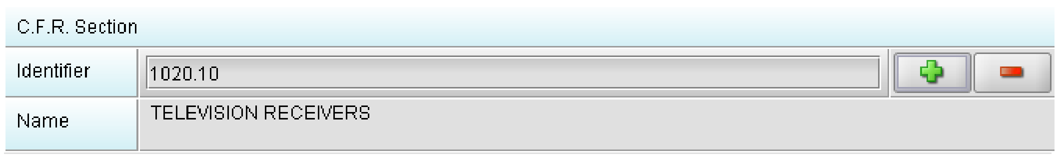
	Action	Graphic
1.	Click the **Select Item** icon. *A Selection List Dialog* box is displayed (as shown below).	

Selection List Dialog Box



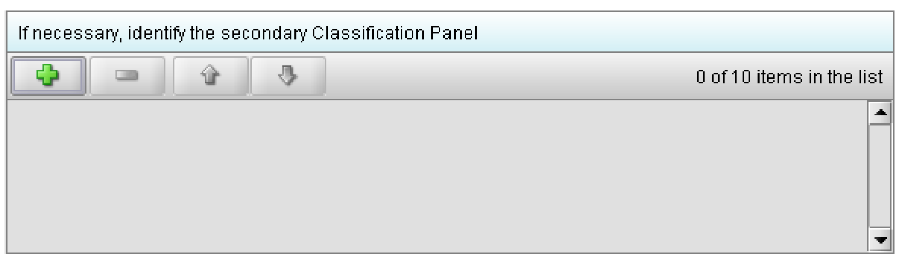
2.	Click to select (highlight) the desired option.

3. 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).



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

5. Repeat steps 1 through 3 to make another selection.

Table	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. 

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.	

Subsection 4.2.2: Question Types – Option Lists

	Action	Graphic
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.	
4.	Repeat steps 1 and 2 to make another selection or enter text responses into the table.	

Subsection 4.2.3: Question Types – File Attachments

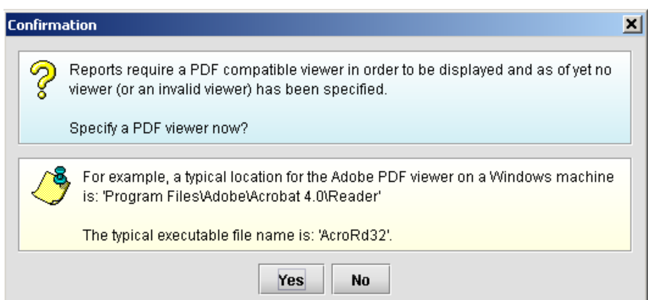
File Attachment

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.

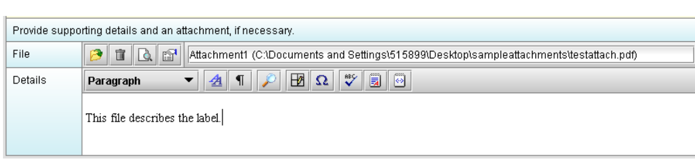
Note that the question itself may be restricted to only allow certain file types to be attached (e.g., PDF only or a combination, such as PDF and/or Excel file types only).

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.



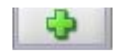
Location of File Attachment

Indicates Rich Text Editor

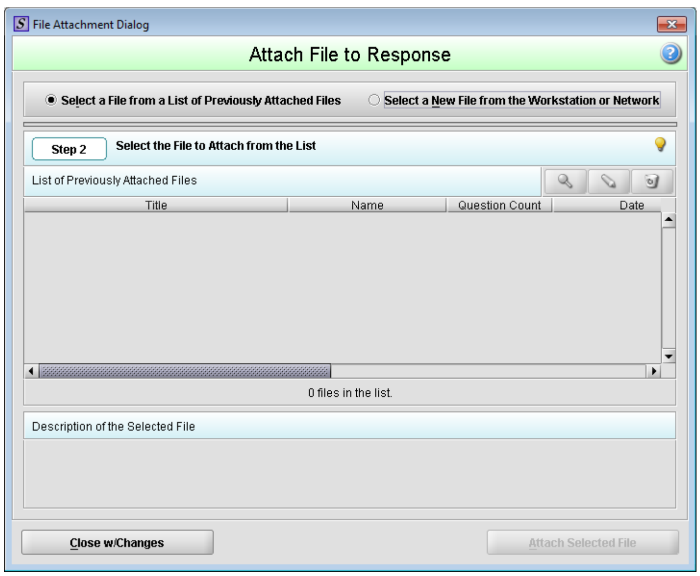
Subsection 4.2.3: Question Types – File Attachments

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.

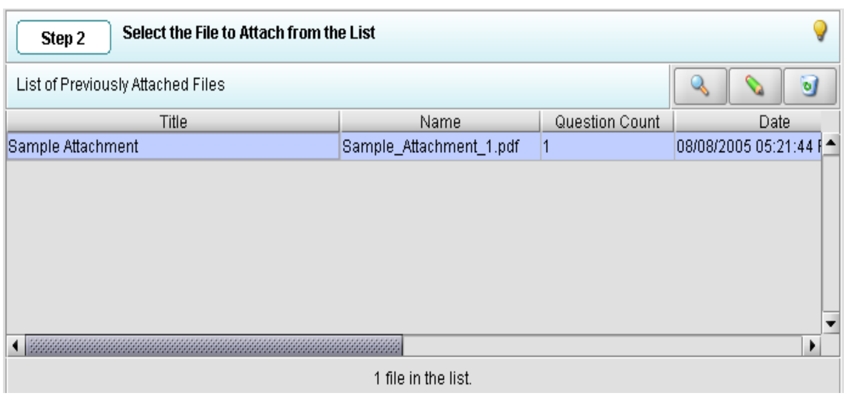
   Note: The wizard defaults to the method "Select a File from a List of Previously Attached Files" if the master file list contains any files to choose from. If there are no files in the master file list, it will default to the method “Select a New File from the Workstation or Network”.

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”.

3. **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



4. 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.

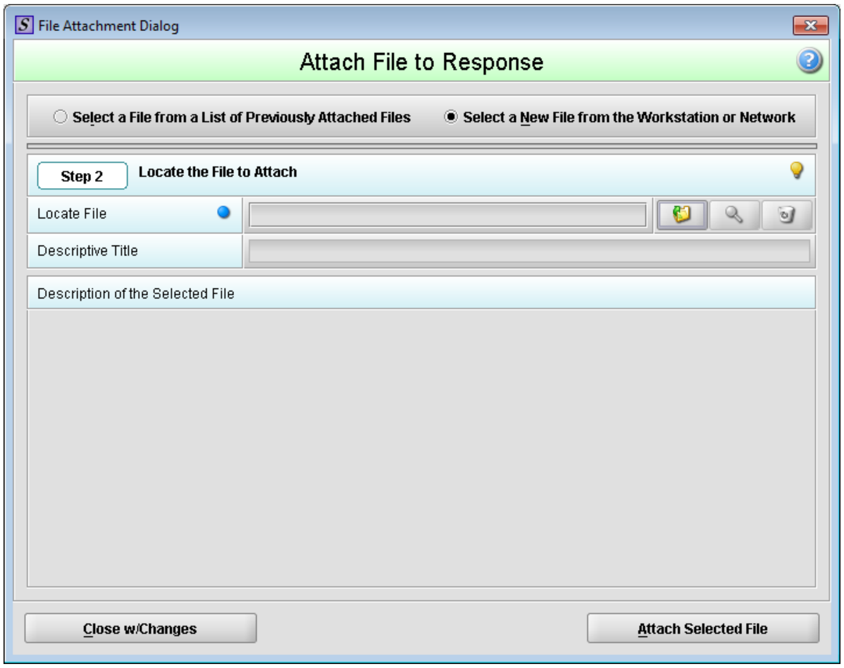
5. **Step 2: Select the File to Attach According to the Method Chosen --** *Select a New File from the Workstation or Network.*

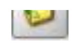
   If the file cannot be located in the master list, then the method chosen in Step 1 must be “Select a New File from the Workstation or Network”.

6. **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

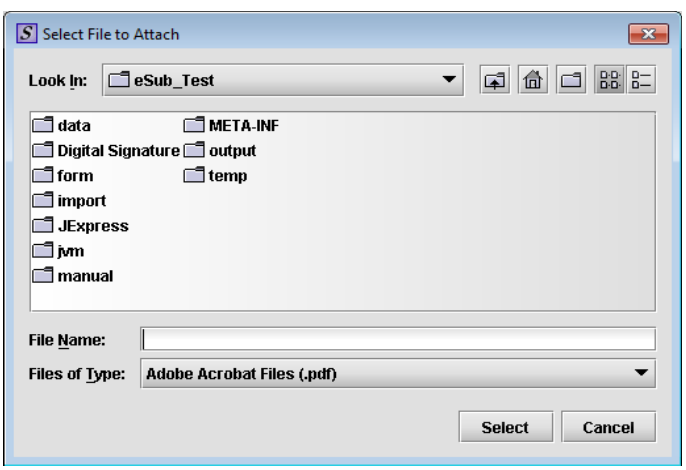
Select a New File from the Workstation or Network



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



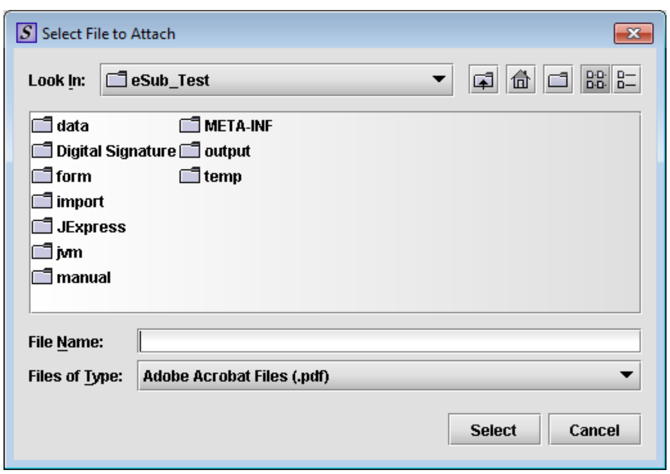
8. Verify that the correct file type is selected in the **Files of Type** drop down located below the **File Name** field. Only those files of the type chosen will appear in the display pane for you to select. The **Files of Type** is defaulted to **Adobe Acrobat Files (.pdf)**.

   <u>Note:</u> 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).

9. 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.

10. When you locate the desired file, click to select it (highlight). The name of the file appears in **File Name** (as shown below).

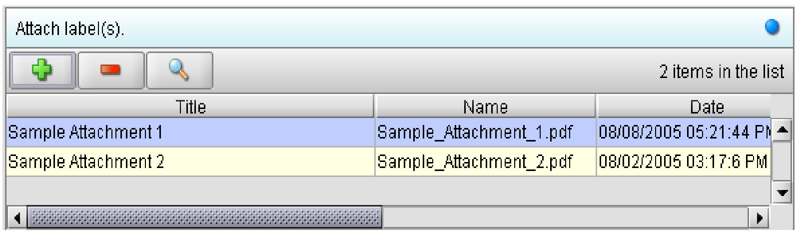
Select File Dialog Box – File Selected



11. Click **Select**. The *Select File to Attach* dialog box closes, and you return to the *File Attachment* dialog box.

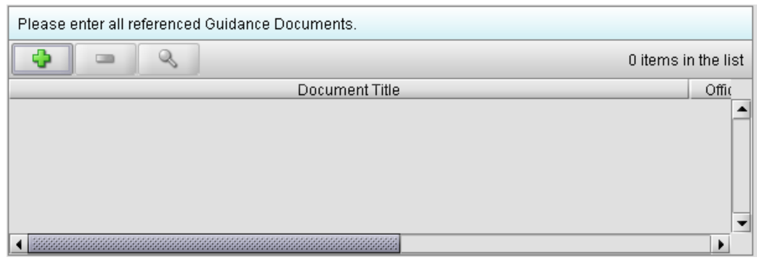
12. Enter a title in **Descriptive Title** (required entry) and a description in **Description of Selected File**, if desired.

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

<table>
<tr>
<td>Multiple File Attachments</td>
<td>
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.


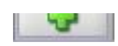
Scroll Bar to view additional details on files
</td>
</tr>
</table>

Subsection 4.2.4: Question Types – Guidance Documents

Guidance Documents	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. 

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

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.

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.

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

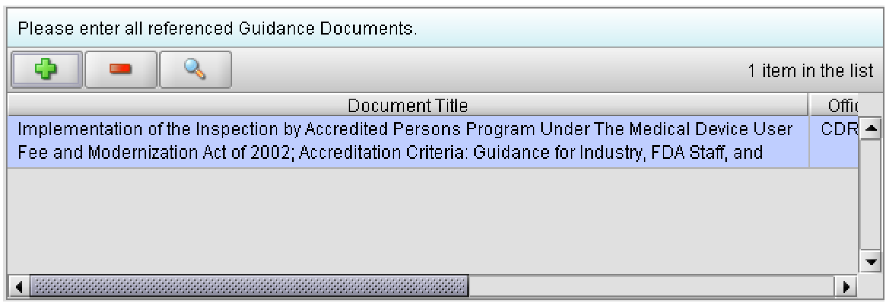
   - Click to select (highlight) a particular guidance document.
   - Click **Select**. The selected document appears in **Guidance Documents currently selected** area of the screen.

   - Repeat the above two items for each desired guidance document.
   - Click **Delete** to remove a guidance document from your selection.

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.

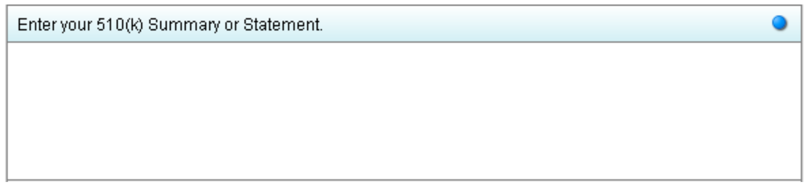
Guidance Document Containing a Response



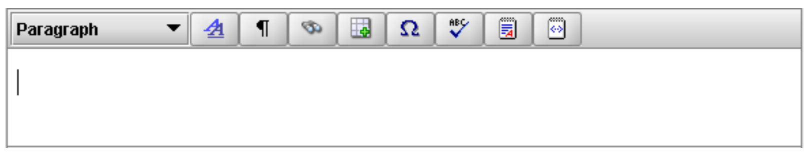
Subsection 4.2.5: Question Types – Text Fields and Messages

Memo (Multi Line Text)

This question type provides an area for you to enter several lines of text (as shown below).

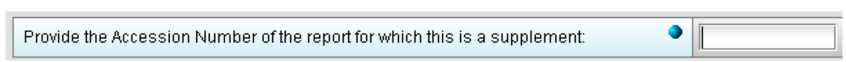


The question may contain a Rich Text Editor which allows you to format what you type (bold, underline), run spell check, or insert a table. The tool bar for the Rich Text Editor will appear after you click in the text area to begin typing.



Text, Single Line

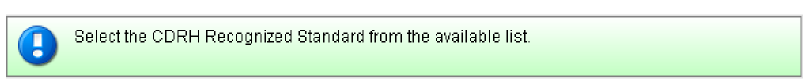
This question type allows you to type in text as a response. Below shows an example of a text question.



Message

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:

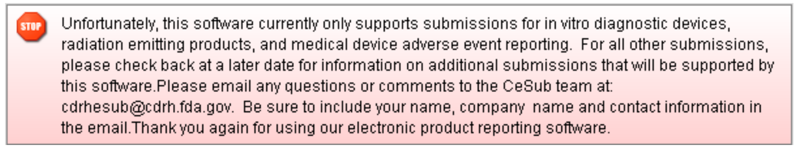
- **Information Message**



- **Error Message**

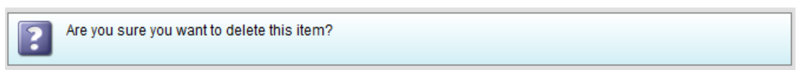
Subsection 4.2.5: Question Types – Text Fields and Messages

- **Stop Message**

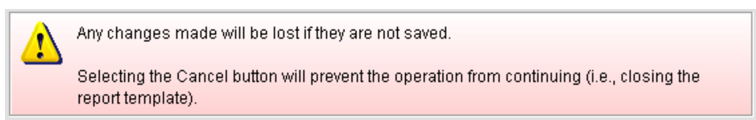


- **Note Message**

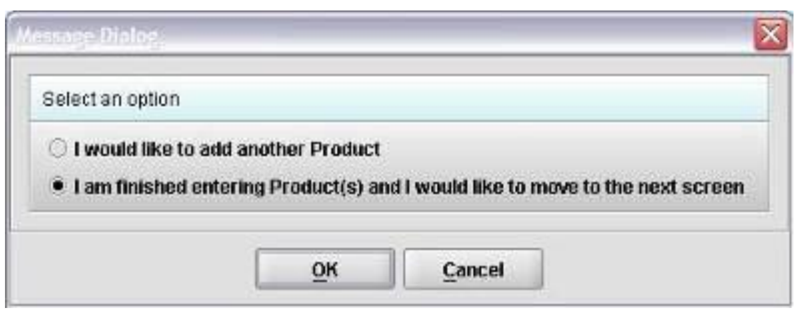
- **Confirmation Message**



- **Warning Message**



- **Missing Data Message**

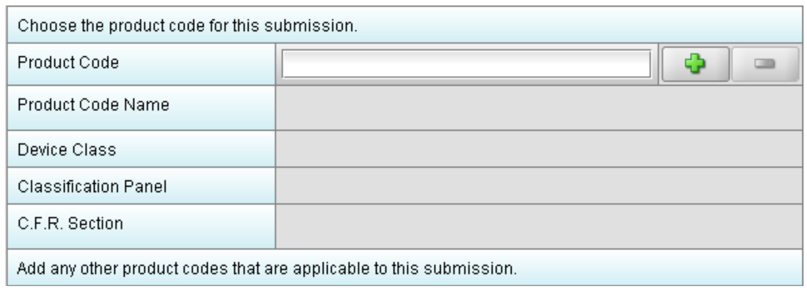


Subsection 4.2.6: Question Types – Product Codes

Product Code (Single)

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.

<u>**Note:**</u> The Product Code is specific to those filing with the Center for Devices and Radiological Health.



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:

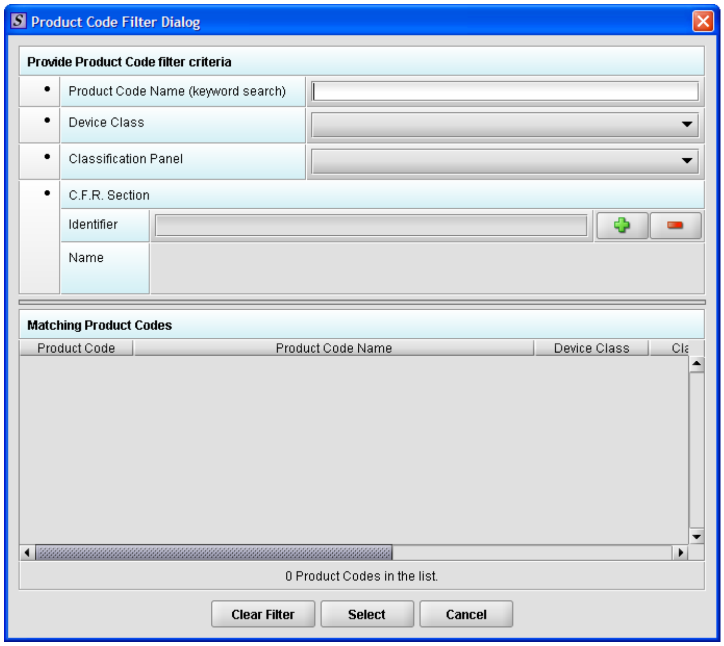
- If you know the three-letter code assigned to your product/device, enter it in the text field. The remaining fields are automatically filled in for you.
- If you wish to remove your entry, click the **delete** icon ( ).
- If you do not know the three-letter code, see the instructions below to search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

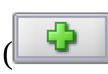
	Action	Graphic
1.	Click the **Select Item** icon. A *Product Code Filter Dialog* box is displayed.	

Product Code Filter Dialog Box



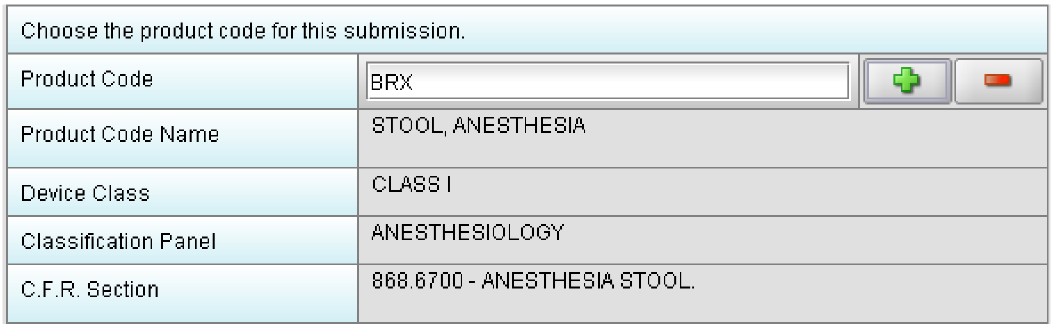
2. Enter a keyword to search the database. You will be provided a list of product codes from which to choose in the **Matching Product Codes** portion of the dialog box.

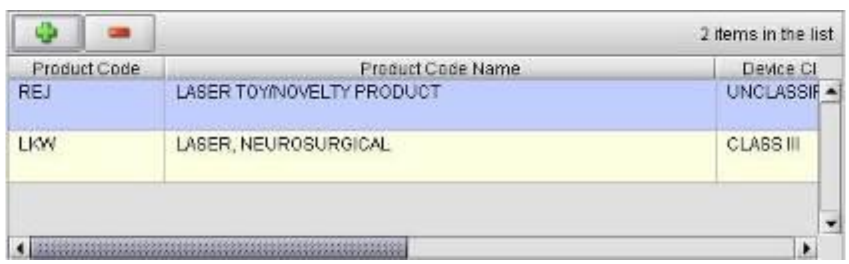
3. To further refine your search, **if desired**:

   - 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.

4. 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).



Product Codes (Multiple)	This question type allows you to identify other product codes applicable to the submission. Below is an example of a multiple product code question. 

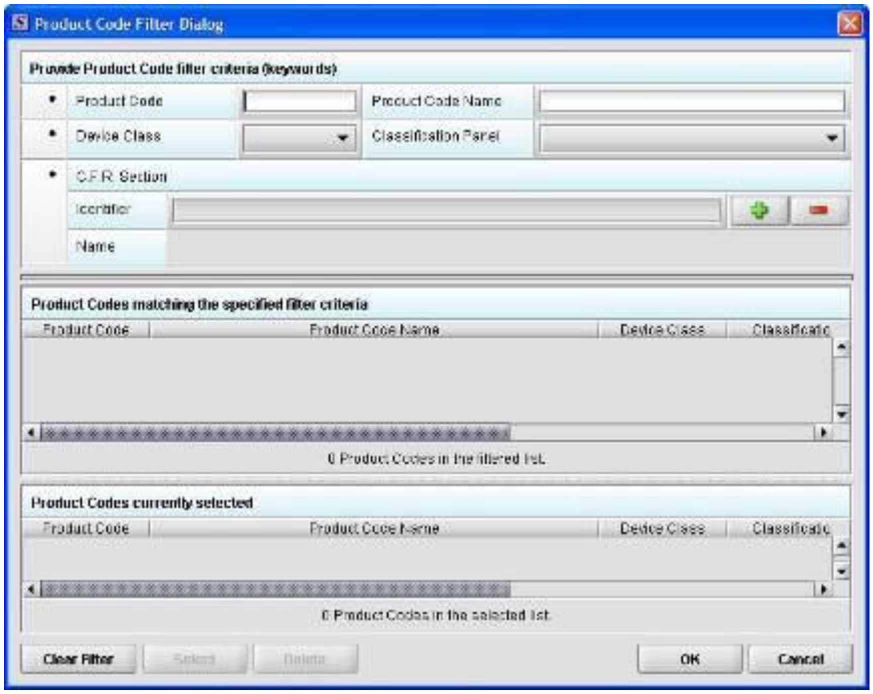
Add Product Codes

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



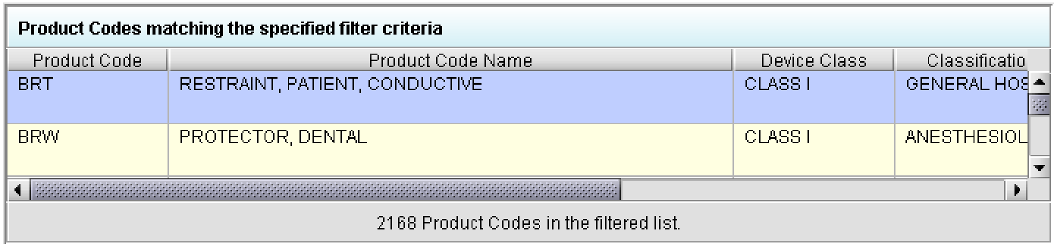
	Action	Graphic
2.	Enter **Product Code** and **Product Code Name** in the appropriate sections.	
3.	Click **OK**.	

Enter Multiple Three-Letter Codes in the Product Code Question

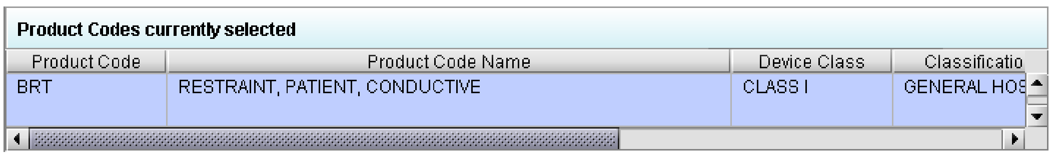
To enter multiple three-letter codes in the product code question, follow the instructions below:

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).	



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



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 in **Product Codes matching the specified filter criteria** portion of the dialog box.	

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**.

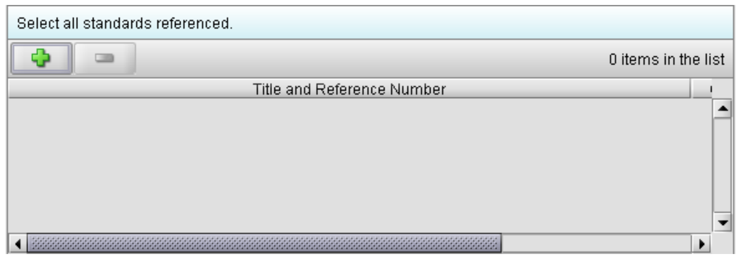
4. Repeat steps 1 and 2 to continue to add product codes.

   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.

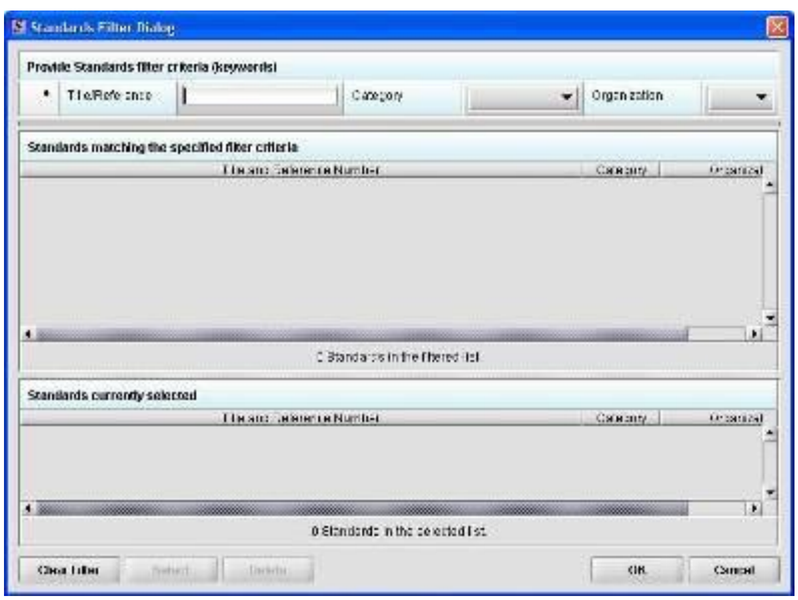
Subsection 4.2.7: Question Types – Standards

Standards	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. 

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



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

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:

<table>
<tr>
<td>List View</td>
<td>
The tabbed view format is indicated by a row of buttons for New, Delete, Delete All, an up arrow, and a down arrow. Directly below this row of buttons is the actual table (as shown below).

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.
</td>
</tr>
<tr>
<td>Details View</td>
<td>


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.
</td>
</tr>
</table>

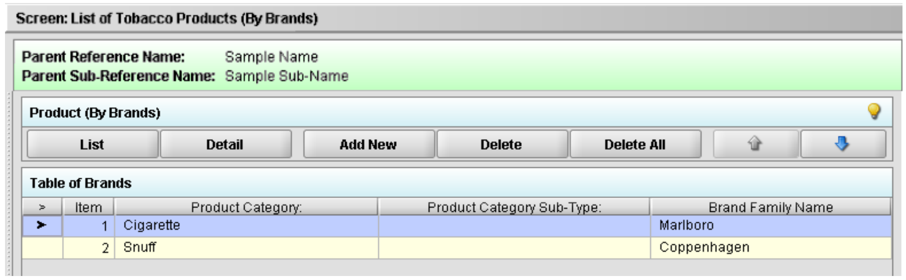
Sections as Tables with a Panel View

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

<table>
<tr>
<td></td>
<td>This format is indicated by a row of buttons for Add New, Delete,</td>
</tr>
</table>

Delete All, an up arrow, and a down arrow. Directly below this row of buttons is the actual table (as shown below).

List View

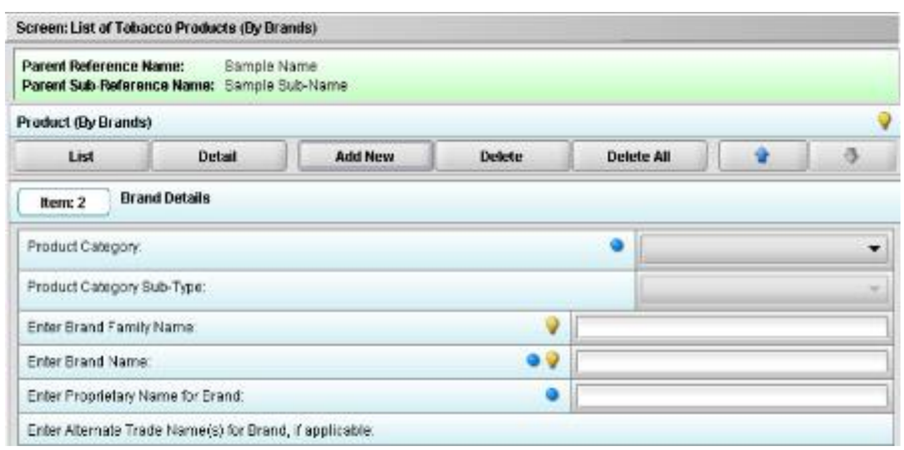


The up and down arrow, as seen below, will allow you to select a specific row when you have multiple entries. You can be sure that the appropriate row is selected as the row will be highlighted in blue and there will be an arrow in the right hand column. Please note the Item number column as this will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

List View with arrows

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.

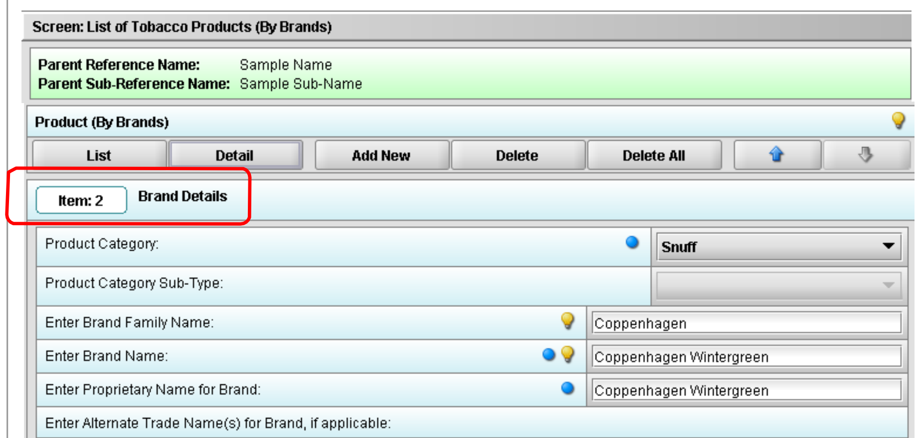
Detail View



To see the items in the table, click **Details**. If you accidentally enter a blank into the table, (by clicking **Add New**, not responding to any

<table>
<tr>
<td>Item Number</td>
<td>
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.

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.



</td>
</tr>
</table>

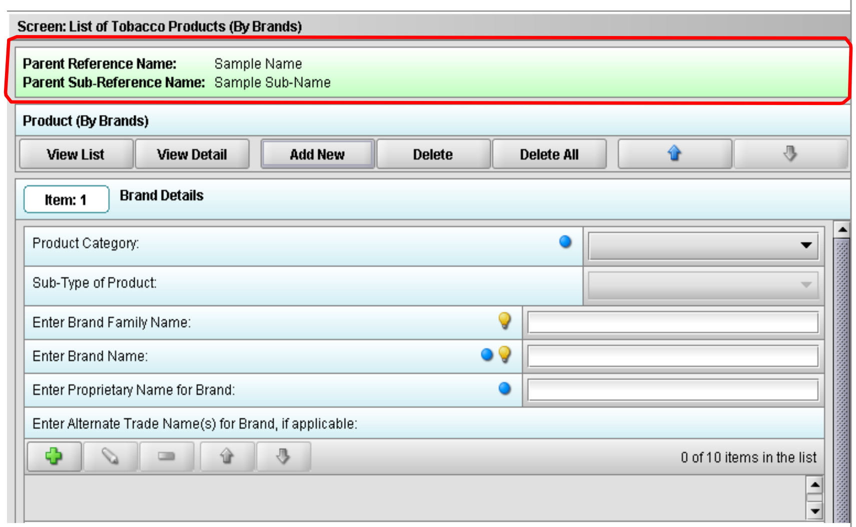
Subsection 4.3: Relationship Across Screens

Relationships Across Parent and Child Screens

Some tabbed and/or panel screens may be linked together through a parent/child relationship, follow the instructions below:

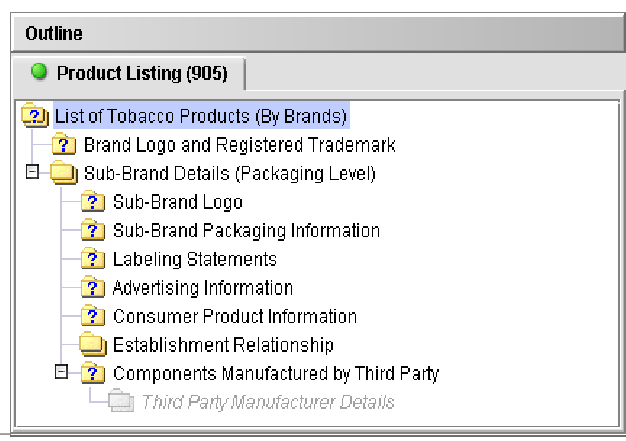
Relationship Header

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.



Expert View Relationship

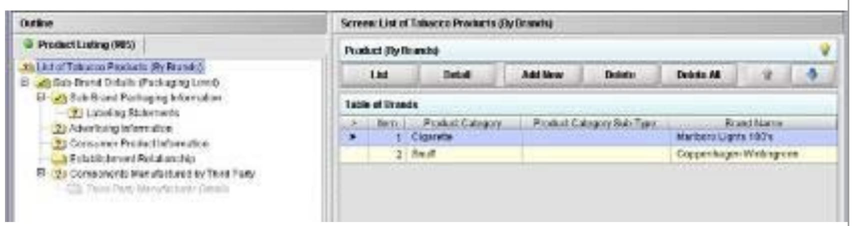
The parent/child relationship can also be seen when in expert view. As mentioned on page 36, the expert view allows the user to navigate through the form using an outline tree located on the left side of the screen. As seen below, the "Brand Logo and Registered Trademark" is a subfolder to the "List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



Relationship Example

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.

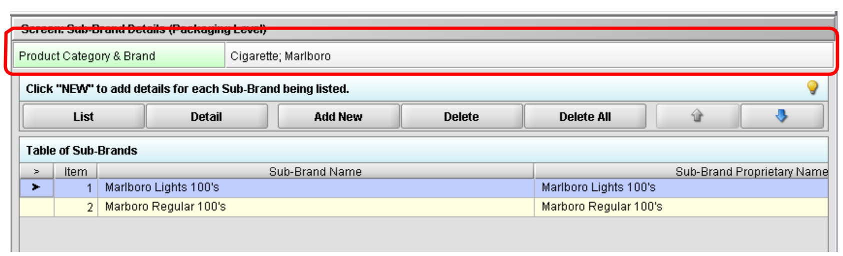
In the expert view on the left, you see the parent folder named “List of Tobacco Products (By Brands)”, below, and the parent folder’s corresponding simple screen.



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.

Parent Header

Note that a new header is displayed in green that reminds you which parent, in this case the product category and brand, you are entering information for.



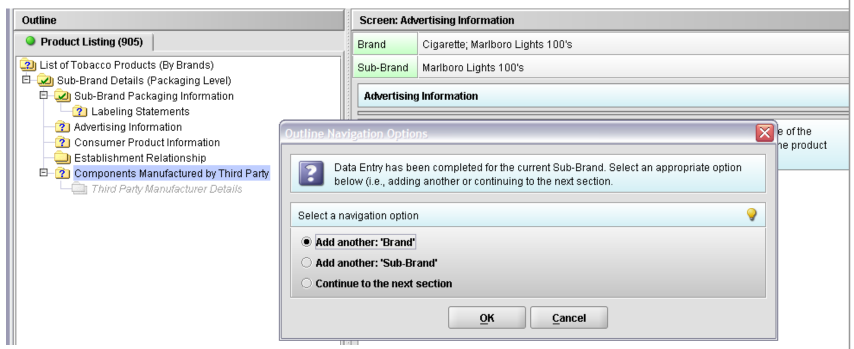
Once you enter information for one sub-brand and have reached the end of the parent/child relationship, a dialogue box, as seen below, will prompt the user if they would like to:

- enter a new parent, (e.g., product category and brand)

OR

- enter a new child to the parent (e.g., the sub-brand),

OR

Navigational Screen	• continue on to the next section. 

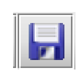
Subsection 4.4: Saving Submission Entries or Changes

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 4.4: 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

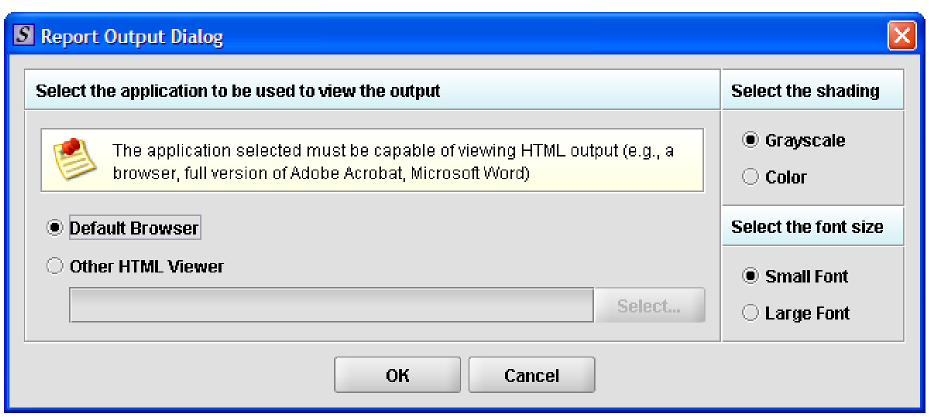
You will only be able to package files for submission as long as no required data is missing from the submission. To determine if any data is missing, you will generate a Missing Data Report. To proceed, the desired submission should be open and displayed on your computer screen.

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



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.)

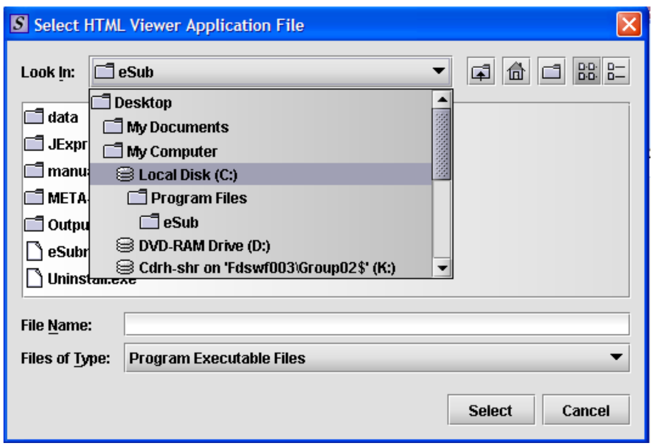
     ⇒ If you selected **Other HTML Viewer**, the **Select** button becomes enabled. Click the **Select** button. You see the *Select HTML Viewer Application File* dialog box (as shown below).

Select HTML Viewer Application File Dialog Box

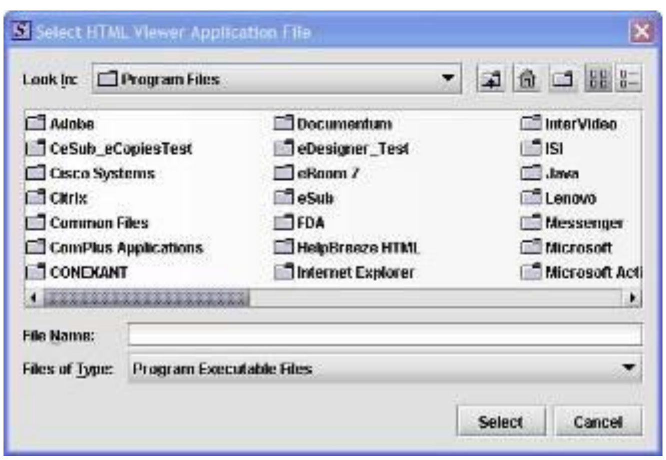
3. • Click in the **Look In** box to navigate to the **executable** (.EXE) of the application to view the HTML. For example, if you want to view the missing data output report in Word 2002, you would navigate using the following path:

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

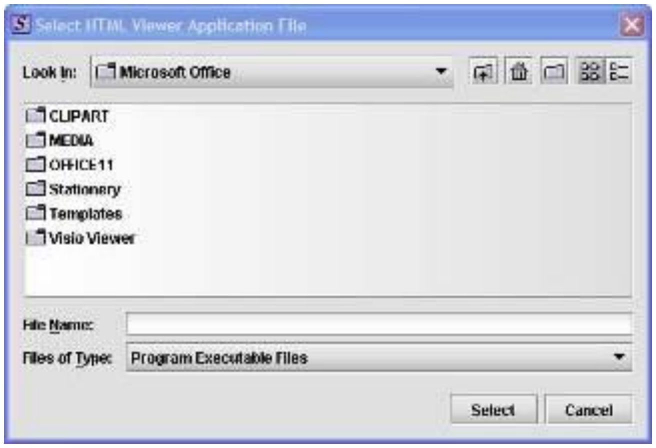
The following screens display an example for the navigation sequence to find Word 2002's executable (winword.exe):



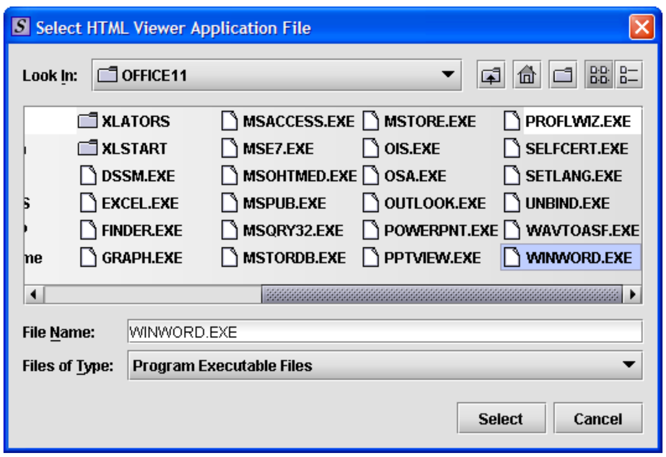
Finding Word's Executable File (Navigation 1)



Finding Word's Executable File (Navigation 2)



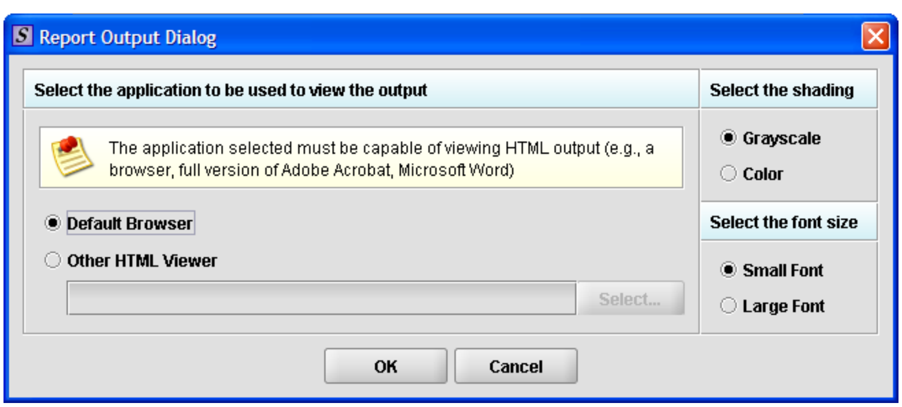
Finding Word's Executable File (Navigation 3)



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).

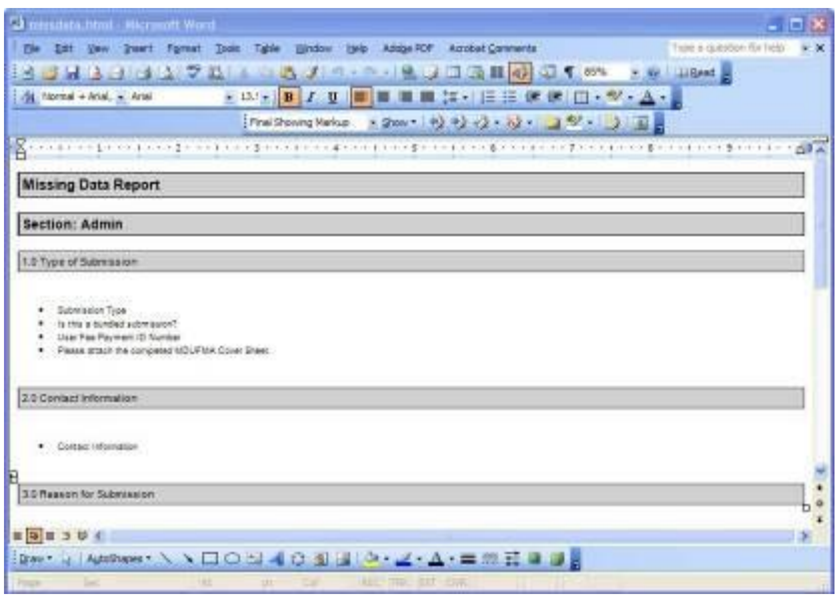
Report Output Dialog Box



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.



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

Subsection 4.5: 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

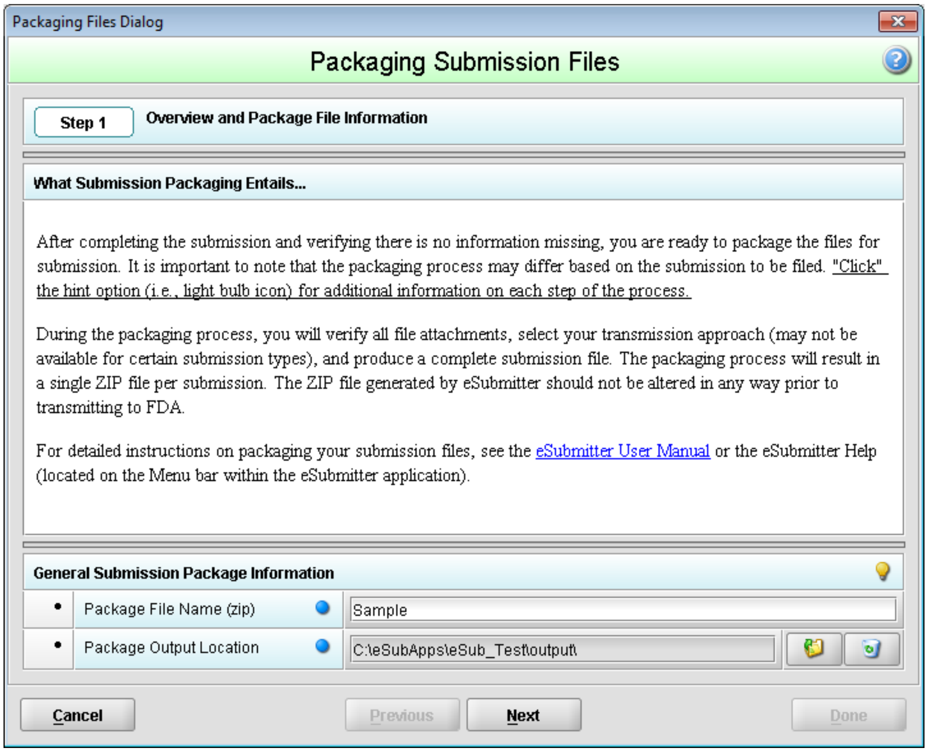
To package files for submission, follow the instructions below.

	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.	

Packaging Files Dialog Box

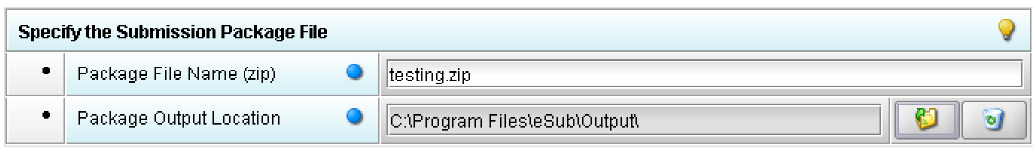


Step 1: Overview and Package File Information

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

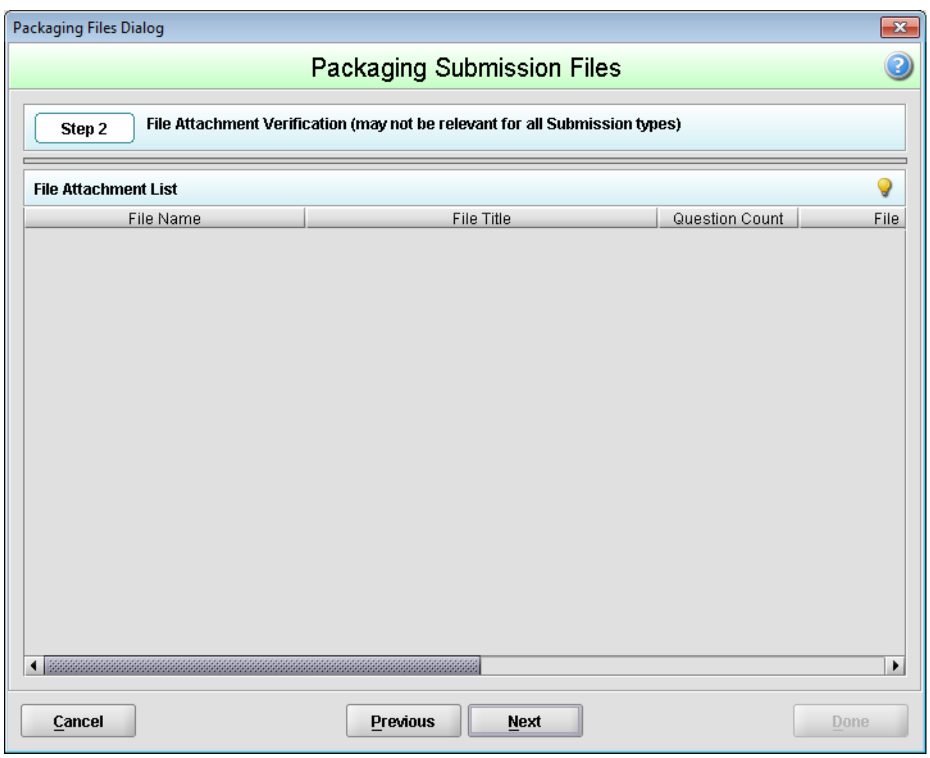
Action	Graphic
1. Specify the submission package file name. ➢ The **Package File Name (.zip)** text box identifies the default zip file name for the submission. (eSubmitter automatically uses the submission name for the zip file.) Make a note of the name for the zip file.	

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**.	



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

Step 2: File Attachment Verification



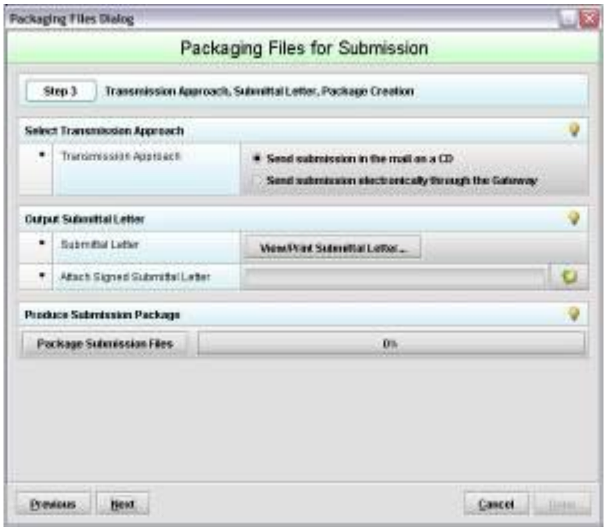
This section lists all file attachments used in the submission.

	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. ➢ **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	
	Cancel and exit the *Package File Dialog* box.	

Step 3: Transmission Approach, Submittal Letter, and Packaging

<u>This section will differ based on the submission you are filing.</u>

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**.



Select Transition Approach (may or may not be applicable)

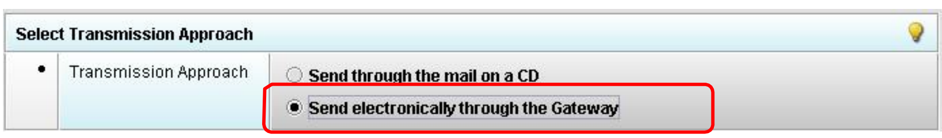
Choose the selected approach to send your submission to FDA.

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

- The 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.

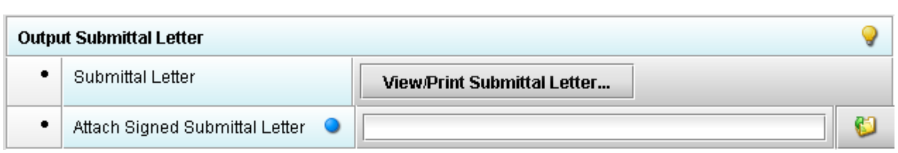
  In addition, if the **Attach Signed Submittal Letter** is available, you must have the capability to scan your signed cover letter in the subsequent **Output Submittal Letter** step (see below).



Output Submittal Letter (may or may not be applicable)

Follow the instructions below for the Output Submittal Letter.

	Action	Graphic
1.	Click the **View/Print Submittal Letter...** button, as shown below.	



2.
   a. Ensure that your submittal letter is accurate.

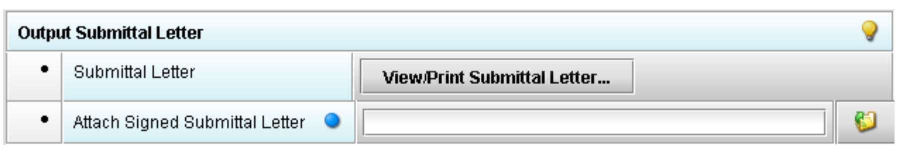
   b. Print and sign the submittal letter.

   c. Prepare to mail the submittal letter (for CD transmission approach)

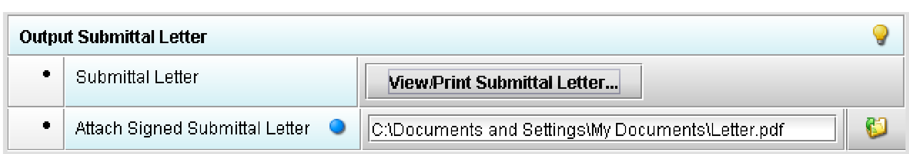
   OR

   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).

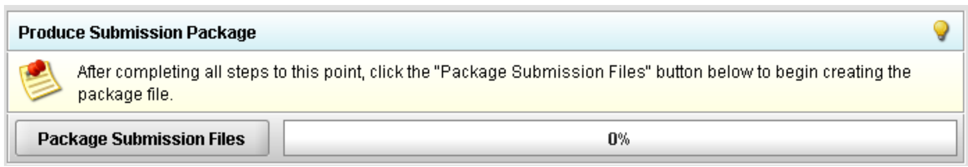


Produce Submission Package (Always available)

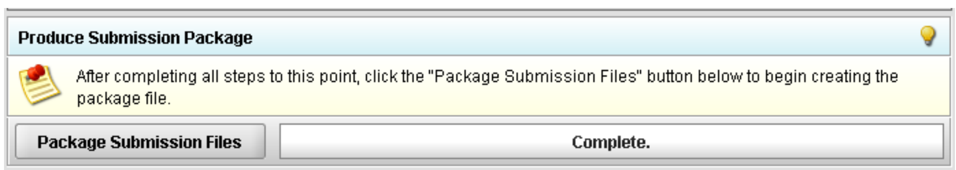
To produce a submission package, follow the instructions below.

Subsection 4.5: Completing a Submission (Packaging Submission Files)

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

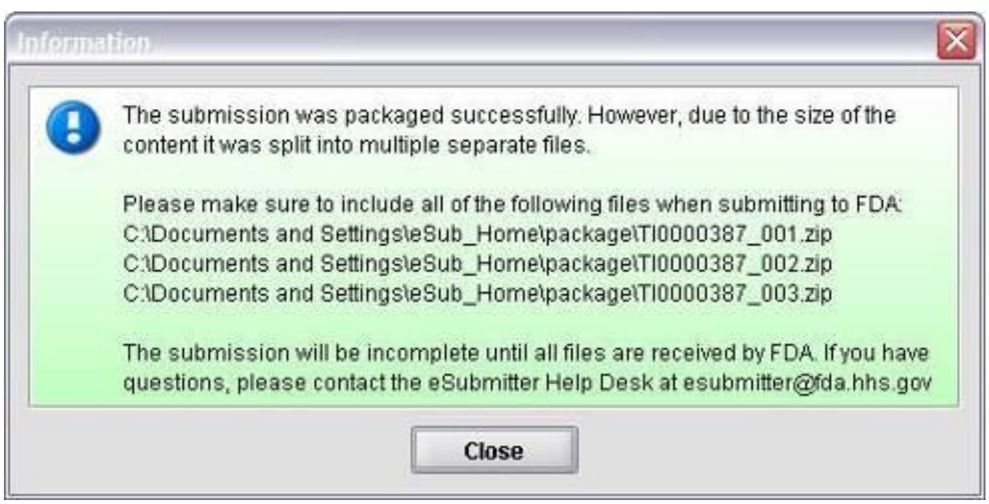


2.	**NOTE:** Once the submission has packaged successfully, the status bar will indicate that the packaging is complete (as shown below).	



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 4.5: Completing a Submission (Packaging Submission Files)

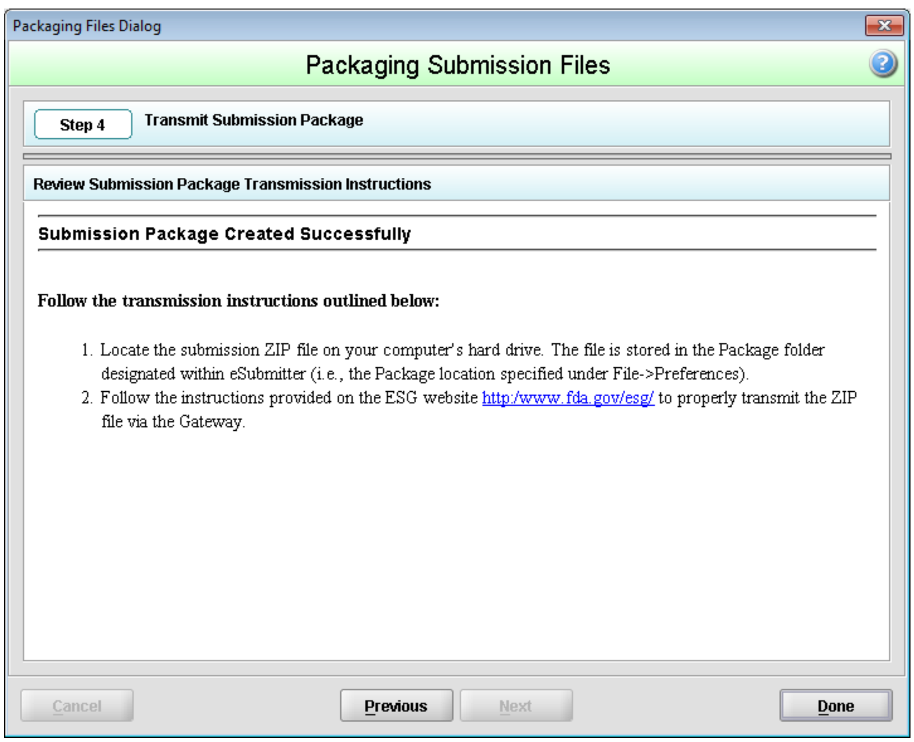
3. Click **Next** to proceed to **Step 4** to view the transmission instructions related to your submission.

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



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.

	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.**

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.

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.

For additional information, please refer to the Quick Guide *"Packaging and Transmission Guidelines for Participating eSubmitter Programs"*

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	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: • Limit the number of fonts used in each document • Use only True Type or Adobe Type 1 fonts • Avoid customized fonts. Resizing a document because the contents are too small to read is inefficient.

	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. Blue font may be used or 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. 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.
Page Numbering	If a submission includes more than one document, you need not provide pagination for the entire submission. Include page numbers only for individual documents. It is easier to navigate though 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.
File Size	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. If you have questions about file size, please contact technical support at esubmitter@fda.hhs.gov to ensure the file size is acceptable.
Document Properties: Description Tab	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.
Document Properties: Initial View Tab	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.
Document Properties: Security	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.

Indexing PDF Documents	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. 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.
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Introduction

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