

# FDA eSubmitter

## User Manual



**Document Version 5.1**

**February 5, 2012**

## 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 4.9	March 3, 2011	Updated to include an appendix to reflect CVM specific file specifications
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.

# FDA eSubmitter

## Table of Contents

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<b>Section 1: Introduction.....</b>	<b>1</b>
Contents .....	1
Subsection 1.1: System Background.....	2
Subsection 1.2: About this Manual.....	3
Subsection 1.3: Software Installation .....	4
<b>Section 2: Getting Started.....</b>	<b>7</b>
Contents .....	7
Subsection 2.1: Starting the Software.....	8
Subsection 2.2: Setting User Preferences .....	14
Subsection 2.3: Creating a New Submission .....	26
Subsection 2.4: Copy an Existing Submission to Create a New Submission.....	30
Subsection 2.5: Re-open an Existing Submission.....	33
<b>Section 3: Interface.....</b>	<b>34</b>
Contents .....	34
Subsection 3.1: Application Window .....	35
Subsection 3.2: Toolbar .....	40
Subsection 3.3: Menu Bar - Output .....	42
Subsection 3.4: Menu Bar - Tools .....	43
<b>Section 4: Preparing a Submission.....</b>	<b>50</b>
Contents .....	50
Subsection 4.1: Entering Submission Information .....	51
Subsection 4.2.1: Question Types – Address and Contact Information .....	53
Subsection 4.2.2: Question Types – Option Lists.....	56
Subsection 4.2.3: Question Types – File Attachments .....	59
Subsection 4.2.4: Question Types – Guidance Documents .....	65
Subsection 4.2.5: Question Types – Text Fields and Messages .....	68
Subsection 4.2.6: Question Types – Product Codes .....	70
Subsection 4.2.7: Question Types – Standards.....	76
Subsection 4.2.8: Question Types – Sections as Tables.....	78
Subsection 4.3: Relationship Across Screens .....	81
Subsection 4.4: Saving Submission Entries or Changes.....	84
Subsection 4.4: Completing a Submission.....	85
Subsection 4.5: Completing a Submission (Packaging Submission Files).....	90
<b>Section 5: FDA Recommended PDF File Specifications .....</b>	<b>102</b>
<b>Section 6: User Support .....</b>	<b>108</b>
<b>Appendix .....</b>	<b>109</b>
CVM Recommended File Specifications.....	109

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# Section 1: Introduction

## Contents

This section contains the following topics:

<b>Topic</b>	<b>See Page</b>
System Background	2
About this Manual	3
Software Installation	4

## Subsection 1.1: System Background

### **Introduction**

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

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

## Subsection 1.2: About this Manual

### Introduction

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

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

- **Section 1** provides an introduction and explains the requirements for running eSubmitter software, uninstall instructions, installation instructions, installation instructions for Microsoft Vista users, 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

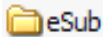
- Windows Operating System
- Adobe Acrobat Reader v5.0 or greater.
- 30 MB of disk space
- Access to a Compact Disk-Recordable drive (CD-R Drive)
- Software capable of viewing Rich Text, such as a Web browser, Microsoft Word, or Adobe Acrobat (full install version, not the Reader)

### Uninstall Instructions

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

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

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

Action	Graphic
1. Use Windows Explorer to navigate to the location of the <b>eSub</b> file folder on the workstation.	
2. Delete the <b>eSub</b> 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

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Action	Graphic
1. Click the link for downloading the eSubmitter Software and save the jinstall.zip file to your computer.	
<b>Download eSubmitter Software</b>	
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 <b>C:\Program Files\eSub</b> .	
<b>Notes:</b> 1. You can change the location where the software is installed by changing the file path on the <b>Installation Directory</b> dialog box when it appears.	
2. The software may be installed on a network. eSubmitter has a file locking option that you set to prevent users from accidentally overwriting the work of another. For details, see <i>Networking</i> on page 18.	

### Installation Instructions for Microsoft Vista Users

Compatibility issues have been identified regarding the use of eSubmitter with the Windows Vista operating system. These issues, related to the installation of the software under the “Program Files” directory, can prevent accessibility to data and output files generated by the software. These issues can be averted by relocating the eSubmitter Data and Output folders to a less restrictive directory (e.g., C:\Users\Public\eSub\_Home). These settings can be changed by navigating to the [File > Preferences](#) option within the application.

If you have already upgraded to the Windows Vista operating system or plan to in the future, see [Instructions for Using eSubmitter on Vista](#) on the FDA eSubmitter website for the latest information on successfully installing the tool within Windows Vista.

## Subsection 1.3: Software Installation

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### 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:

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

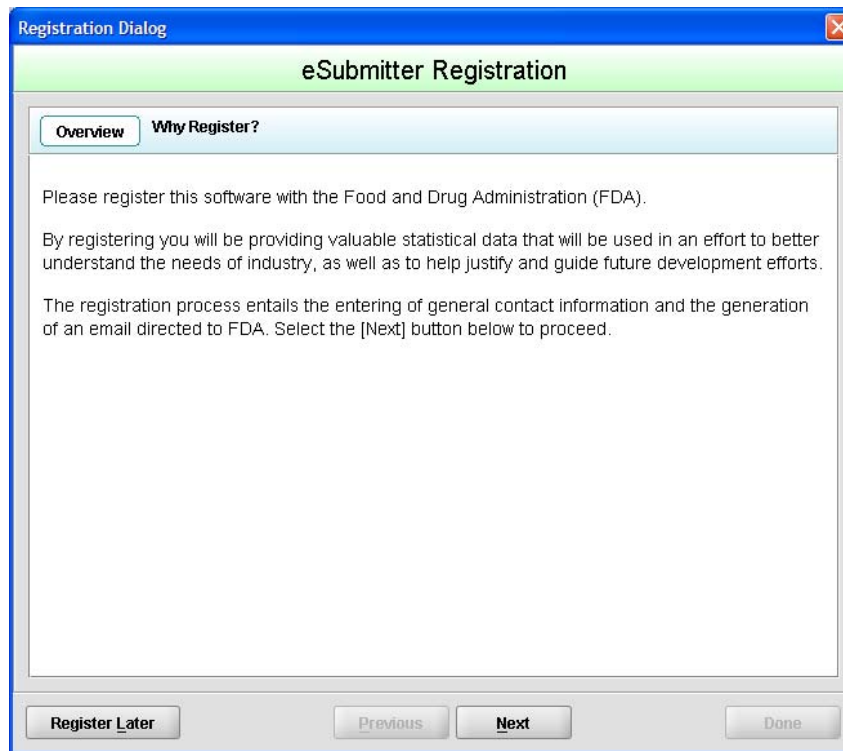
## Subsection 2.1: Starting the Software

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

**Starting the Software** To start up the eSubmitter application, follow the instructions below.

	Action	Graphic
1.	<b>Start</b> , and select <b>Programs &gt; FDA Submission Software &gt; eSubmitter</b> .	
2.	You will see a <i>Registration Dialog</i> box, as shown below.	

### Registration Dialog Box



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



## Subsection 2.1: Starting the Software

### Registration Dialog Box: Contact Information

The screenshot shows a window titled "Registration Dialog" with a green header "eSubmitter Registration". Below the header is a tab labeled "Step 1 Enter Contact Information". The form contains the following fields, all with blue dots indicating they are required:

- Title (Mr., Ms., Dr.):
- First/Given Name:
- Middle Name:
- Last Name:
- Occupation Title:
- Email Address:

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

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.

**Next**

### Registration Dialog Box: Address Information

The screenshot shows a window titled "Registration Dialog" with a green header "eSubmitter Registration". Below the header is a tab labeled "Step 2 Enter Address Information". The form contains the following fields, all with blue dots indicating they are required:

- Establishment Name:
- Country: (radio buttons for "United States of America" and "Other (select below)")
- Address - Line 1:
- Address - Line 2:
- City:
- State, Province, or Territory: (dropdown menu)
- Post Office or Zip Code:

Below these fields is a section titled "Phone Numbers" with a field for "Telephone number:" (format: ( ) - - Ext: ).

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

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

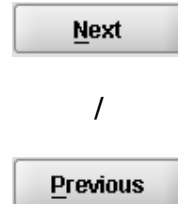
**Next**

## Subsection 2.1: Starting the Software

### 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.



## Subsection 2.1: Starting the Software

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### Registration Dialog Box: Check Results

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

- Question: "Was the registration email sent successfully?"
- Radio buttons:  **Yes the Email was sent successfully**,  **No there was a Problem**
- Text: "If not, what was the issue?"
- Radio buttons:  No email was generated,  All other issues
- Text: "Registration completed. Select the [Done] option below to end the registration process."
- Buttons at the bottom: "Register Later", "Previous", "Next", "Done"

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

---

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

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

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



## Subsection 2.1: Starting the Software

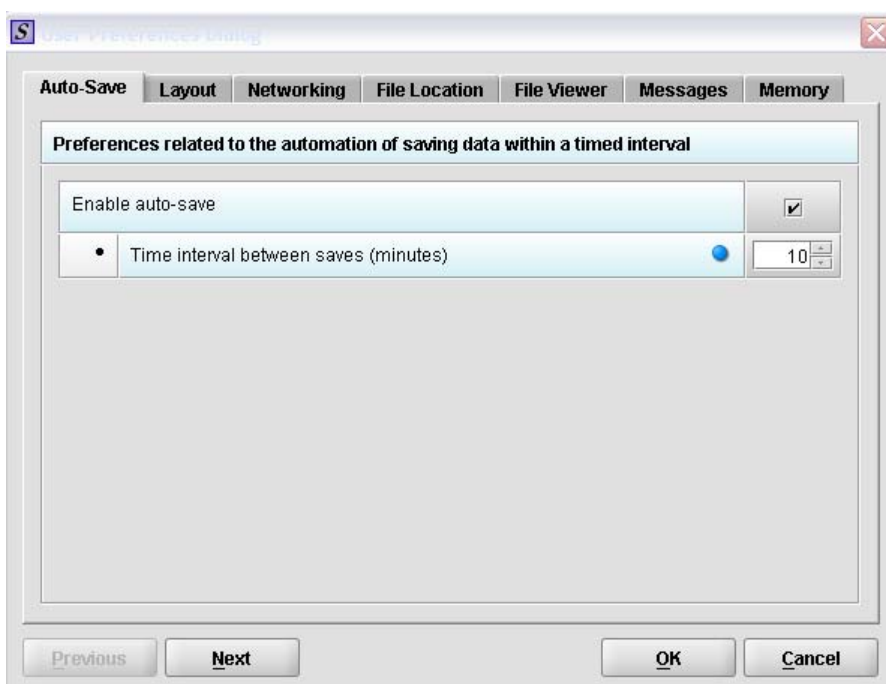
<b>Help Topics</b>		Displays the <i>Help Menu</i> , which provides instructional information and support for utilizing the eSubmitter application.
<b>Forward Navigation Arrow</b>		This arrow allows you to move forward through the <b>Message Tabs</b> .
<b>Backward Navigation Arrow</b>		This arrow allows you to move backwards through the <b>Message Tabs</b> .
<b>Collapse/Expand Arrows</b>		Allows you to collapse and expand the <b>Menu Options</b> portion of the <i>Intro Screen</i> .
<b>Notification Stars</b>		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.
<b>Category Filter</b>		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.
<b>Mark as Read</b>		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).




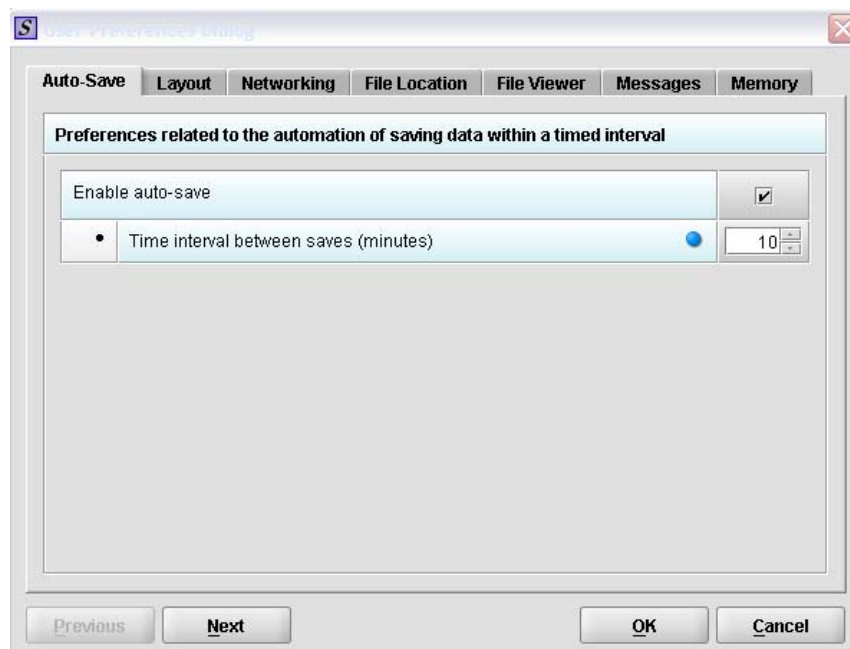
The subsections below will explain how to set preferences for each category.

## 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.

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



To change the auto-save option:

Action	Graphic
1. Check the <b>box</b> 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.	
<b>OR</b>	
Use the up and down arrows to select the interval.	

## Subsection 2.2: Setting User Preferences

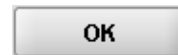
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3. If you want to change or set the layout, click **Next** or the **Layout** tab. See the description for **Layout** below.



**OR**

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



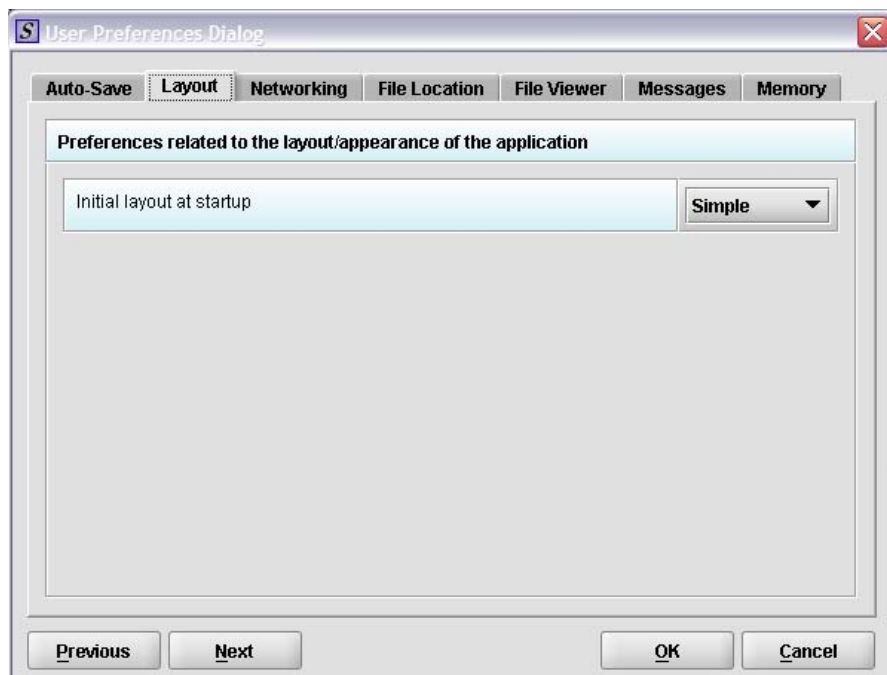
**OR**

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



### Layout


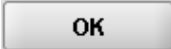

Allows you to set whether you want eSubmitter to open reports in the simple or expert layout when you start up the application. At default, eSubmitter opens reports in the simple layout. For more information, see descriptions in the *Application Window* section on page 35.



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

## Subsection 2.2: Setting User Preferences

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

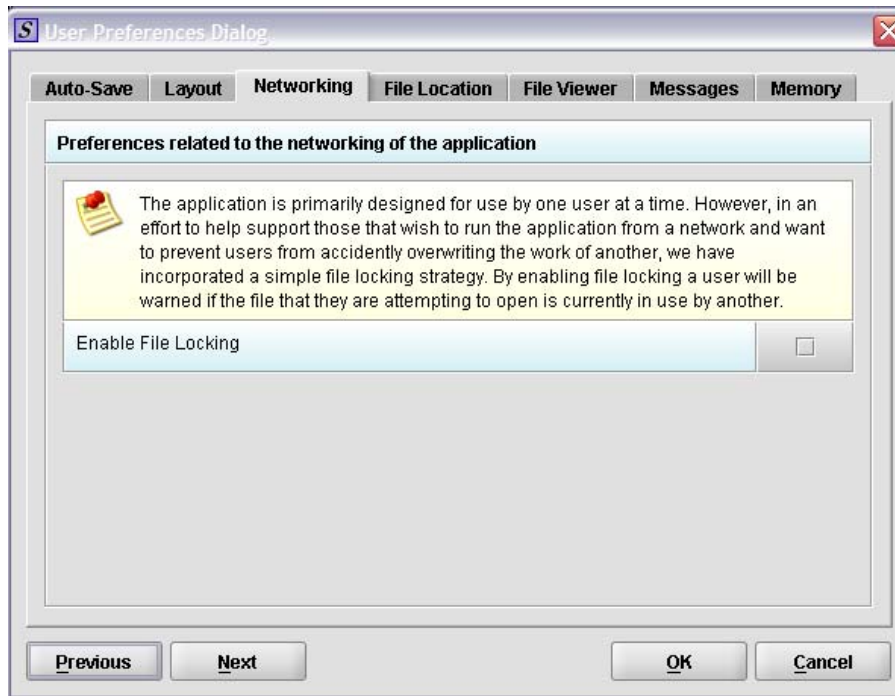
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## Subsection 2.2: Setting User Preferences

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### 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 <b>Enable File Locking</b> checkbox (to turn file locking on) or clear the checkbox (to turn file locking off).	<input checked="" type="checkbox"/>

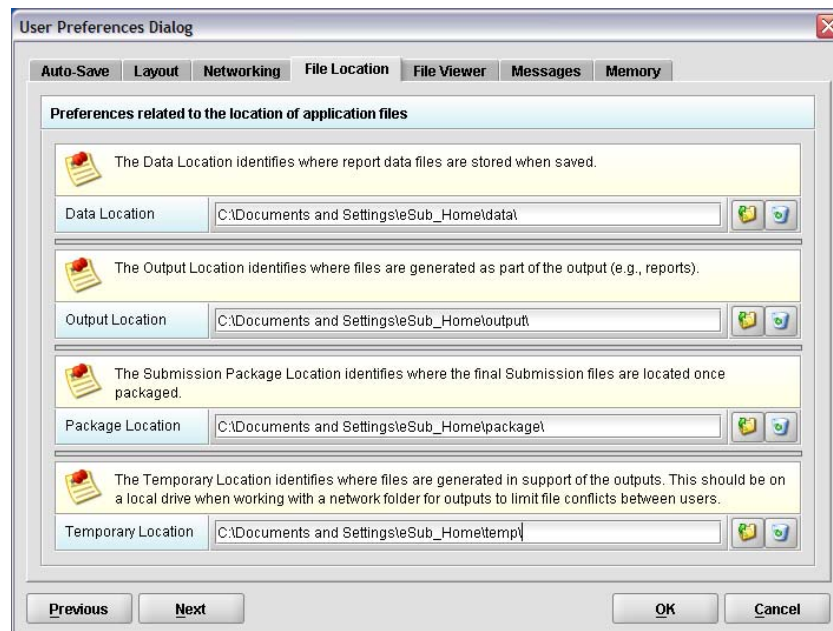
---

## Subsection 2.2: Setting User Preferences

Action	Graphic
2. If you want to change the settings for networking, click <b>Next</b> or the <b>File Location</b> tab. See the description for <b>File Location</b> below.	
<b>OR</b>	
If you are finished and satisfied with your changes, click <b>OK</b> to close the <i>User Preferences Dialog</i> box with your changes saved.	
<b>OR</b>	
Click <b>Cancel</b> to close the <i>User Preferences Dialog</i> 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 90.



To change the file location for each of the folders:

## Subsection 2.2: Setting User Preferences

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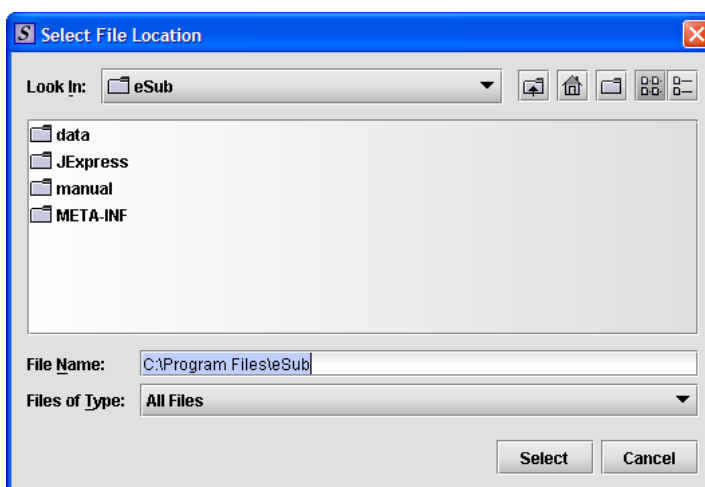
### Action

### 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.

A rectangular button with the word 'Select' in a bold, sans-serif font.

#### Recommended Location:

**If installed on a Network drive (on Vista or 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 Vista):** data and output files should be hosted in the following location: **C:\Users\Public\eSub\_Home\**.

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



## Subsection 2.2: Setting User Preferences

---

**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.

**Next**

**OR**

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

**OK**

**OR**

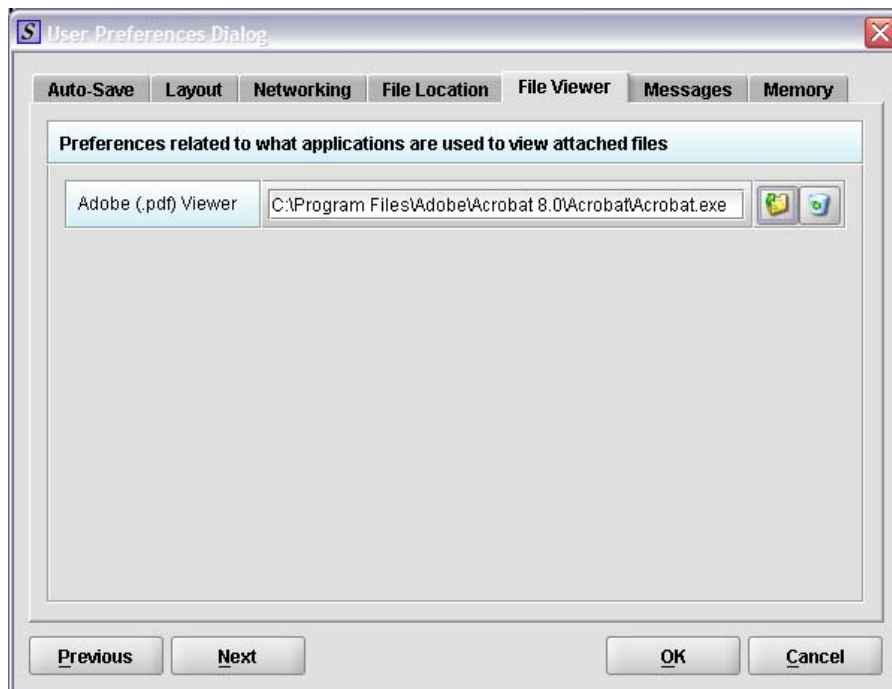
Click **Cancel** to close the *User Preferences Dialog* box without saving any changes.

**Cancel**

---

### 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

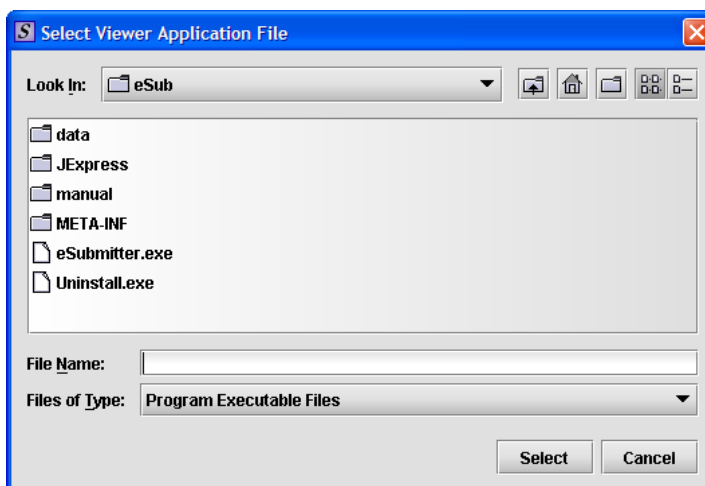
### Action

### 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

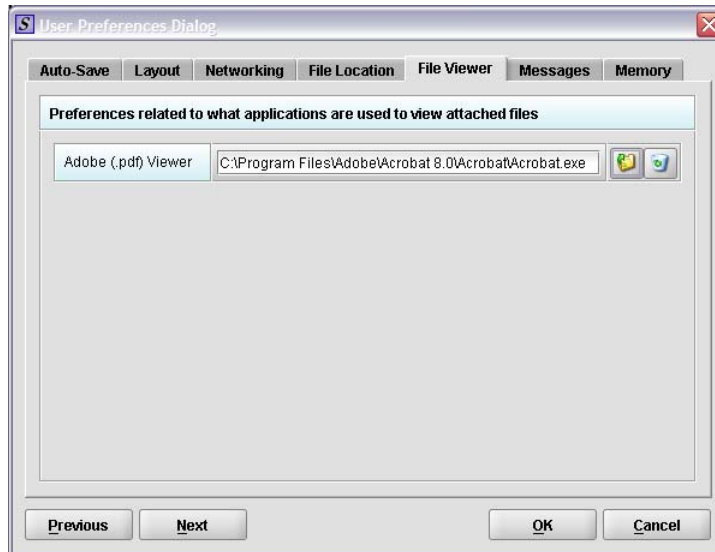


2. Click in the **Look In** box, and navigate to the file folder for Adobe Acrobat or the Acrobat Reader. The location is usually either:
  - **Program Files > Adobe > Acrobat > Acrobat.exe**
  - **Program Files > Adobe > Reader > AcroRd32.exe**
3. Highlight (select) **Acrobat.exe** or **AcroRd.exe** and click **Select**. The **File Viewer** tab in the *User Preferences Dialog* box will appear in the text box as shown below.



## Subsection 2.2: Setting User Preferences

### User Preferences Dialog Box

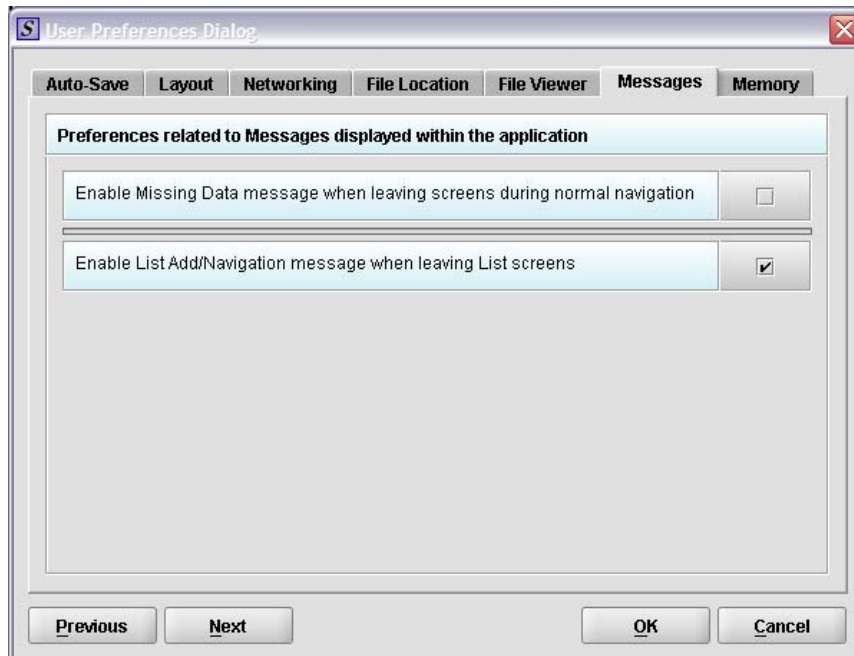


4. Click **OK**.








### 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.



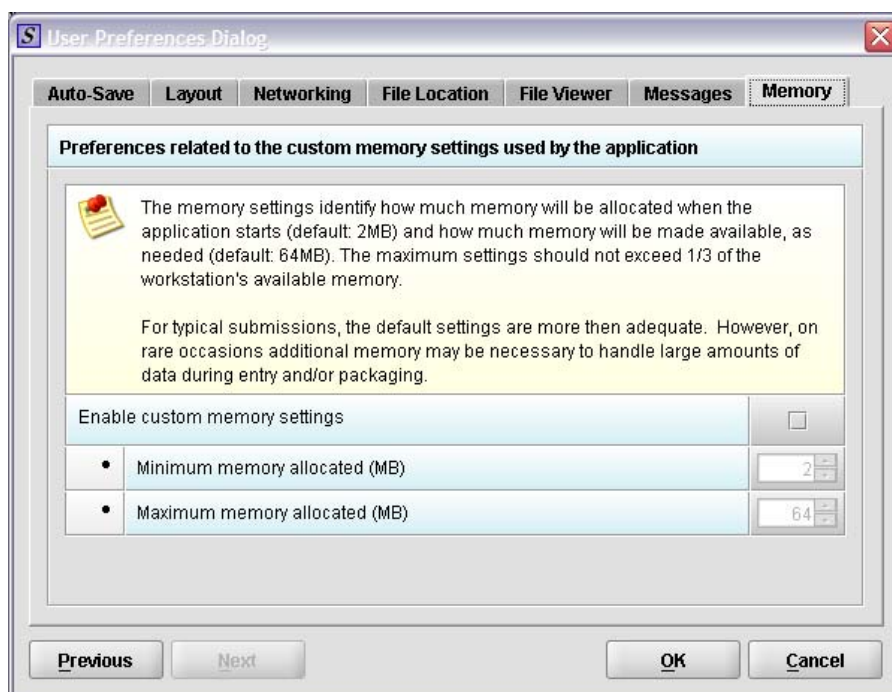
To enable these functions, do the following:

## 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 <b>OK</b> .	

### Memory


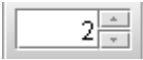
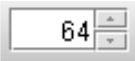

Allows you to identify how much memory will be allocated when the application starts (default: 2MB) and how much memory will be made available, as needed (default: 64MB).



To enable this function, do the following:

## Subsection 2.2: Setting User Preferences

---

Action	Graphic
1. Check the box on the right to enable custom memory settings	
2. To change the minimum memory allocated, use the arrows to the right to increase or decrease or by entering a number in the field.	
3. To change the maximum memory allocated, use the arrows to the right to increase or decrease or by entering a number in the field.	
4. Click <b>OK</b> .	

## Subsection 2.3: Creating a New Submission

### Introduction

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

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

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

### Create a New Submission

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

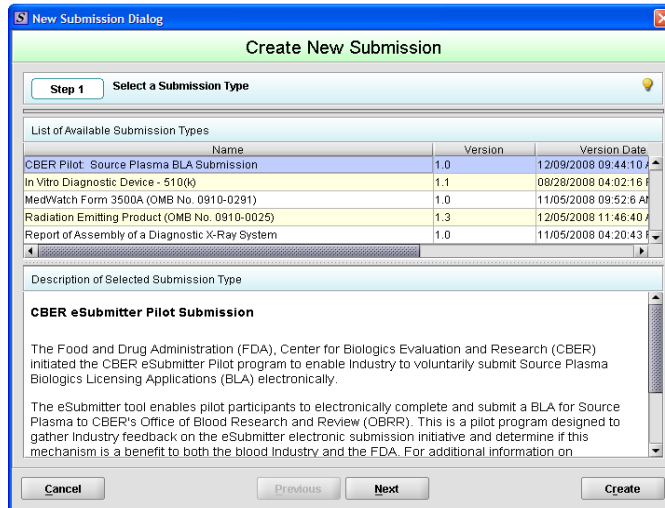
Action	Graphic
1. The eSubmitter application should be open on your computer desktop. If it is open, and you see the <i>Intro Screen</i> , go to step 2. (If it is not open, open the application first by following the instructions in <i>Starting the Software</i> on page 8.)	

## 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**.

## Subsection 2.3: Creating a New Submission

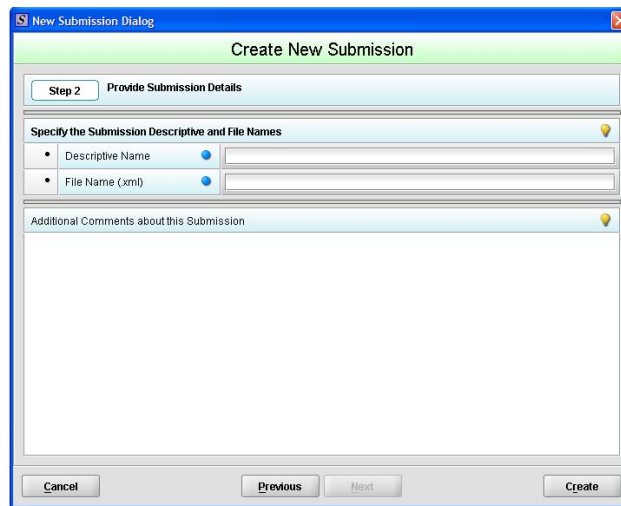
---

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).
-



## Subsection 2.3: Creating a New Submission

---

Action	Graphic
5. When you are finished entering all information in the fields, click <b>OK</b> . 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.

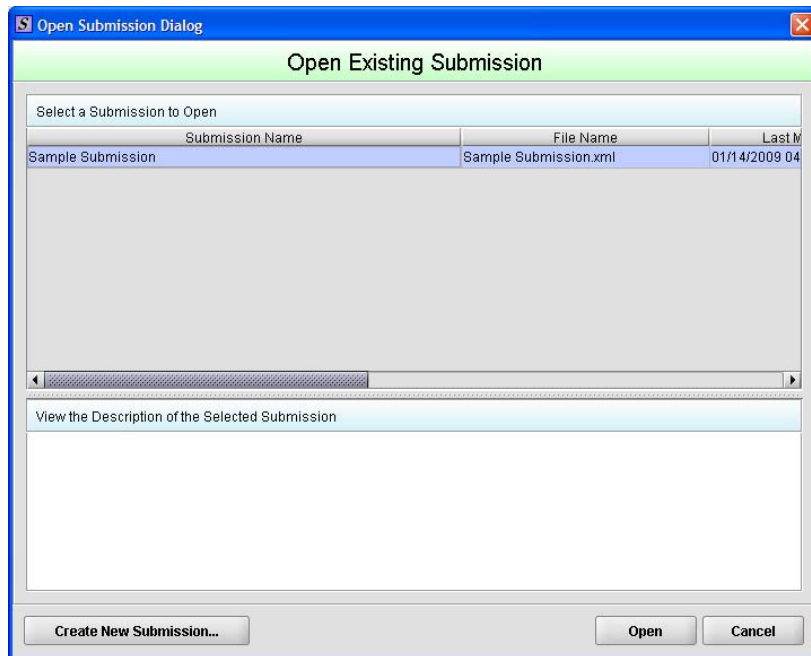
#### Action

#### 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

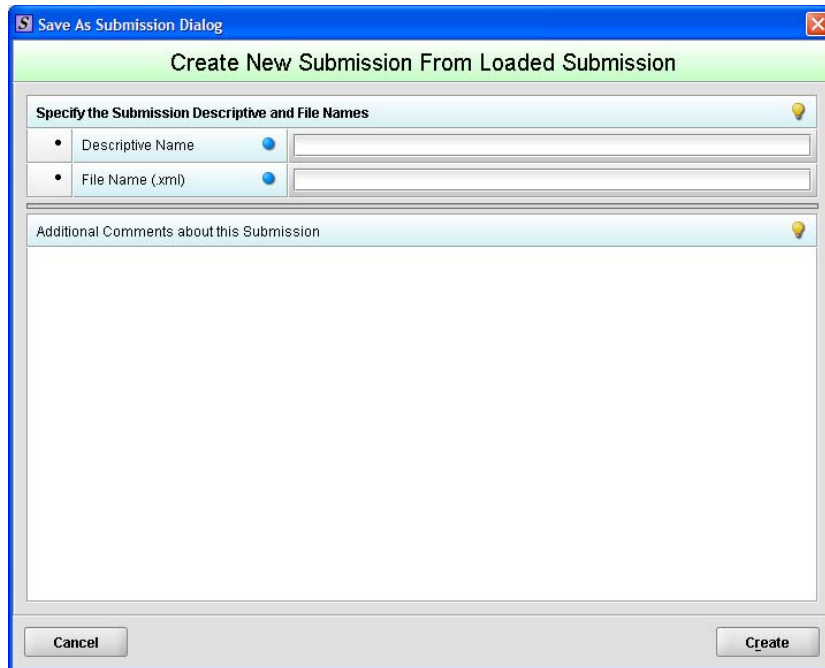


2. Click to select the existing submission report to be used as a template, and click **Open**. The submission report is displayed on your computer.
3. Click **File > Save As**. The *Save Submission As Dialog* box is displayed (as shown below).



## 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 **OK**.



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 51.
-

## Subsection 2.5: Re-open an Existing Submission

### Re-open an Existing Submission

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

#### Action

#### Graphic

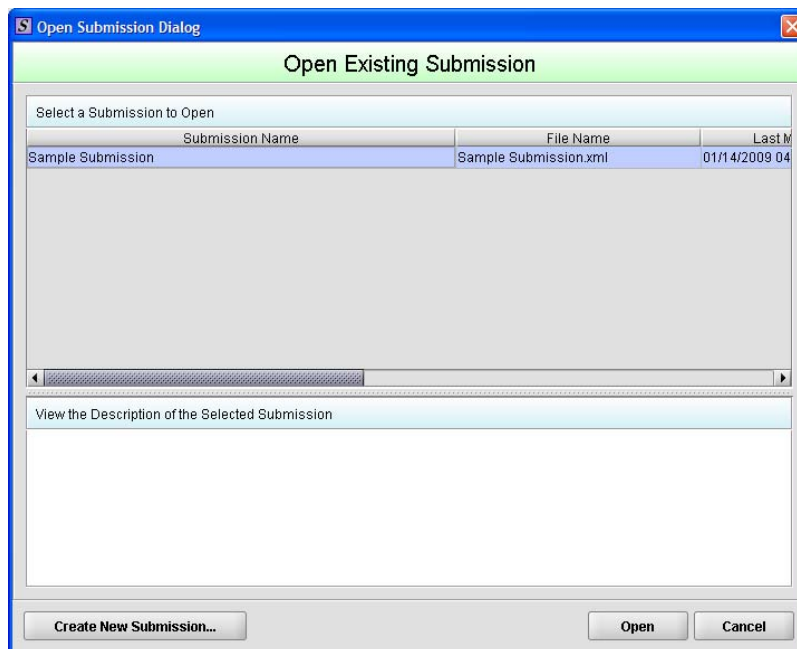
1. Click **File > Open** on the menu bar.

**OR**

Click  on the tool bar.

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

### Open Existing Submission Dialog Box



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



# Section 3: Interface

## Contents

This section contains the following topics:

<b>Topic</b>	<b>See Page</b>
Application Window	35
Toolbar	40
Menu Bar – Output	42
Menu Bar – Tools	43

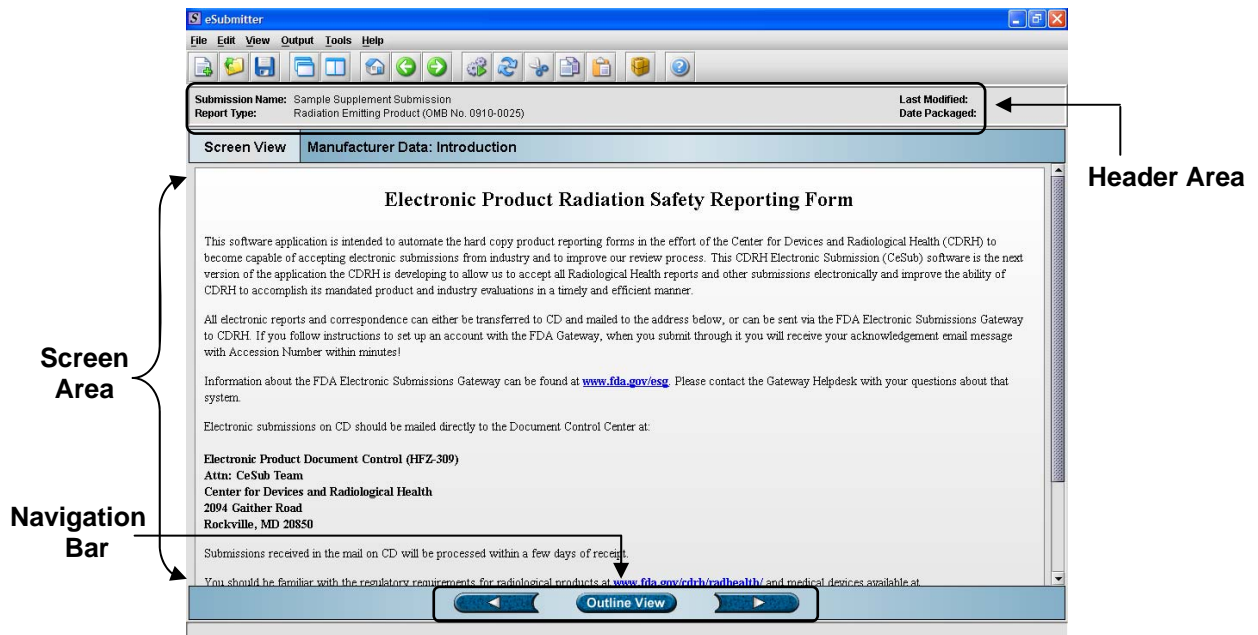
## Subsection 3.1: Application Window

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

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

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

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

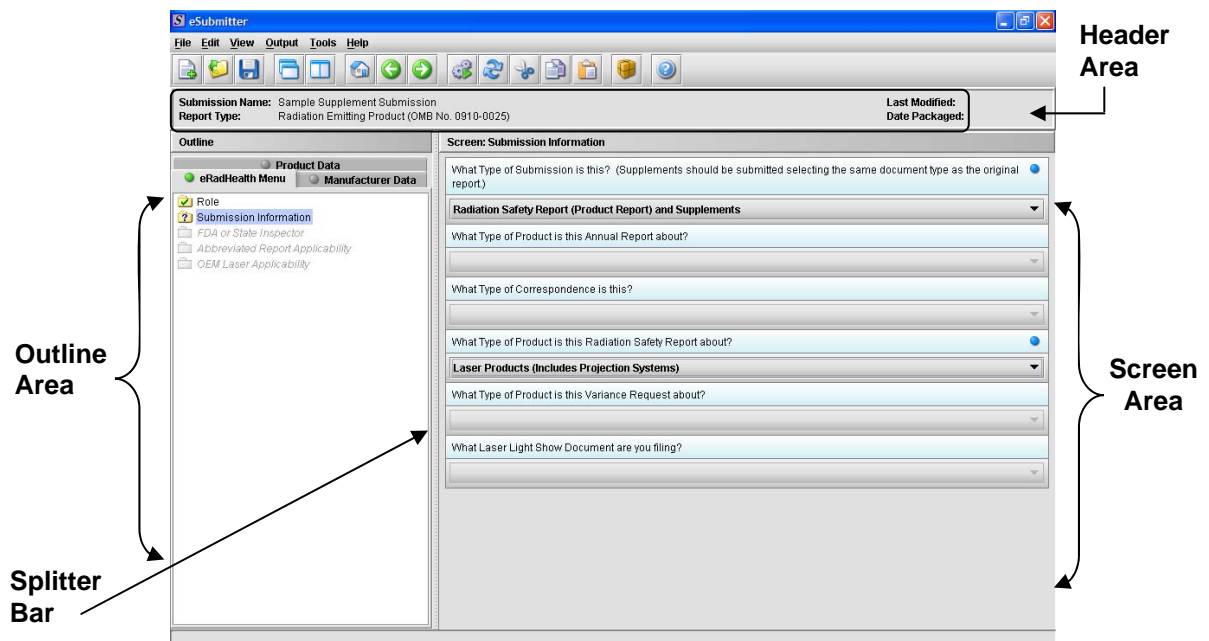


## Subsection 3.1: Application Window

### Expert View

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

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





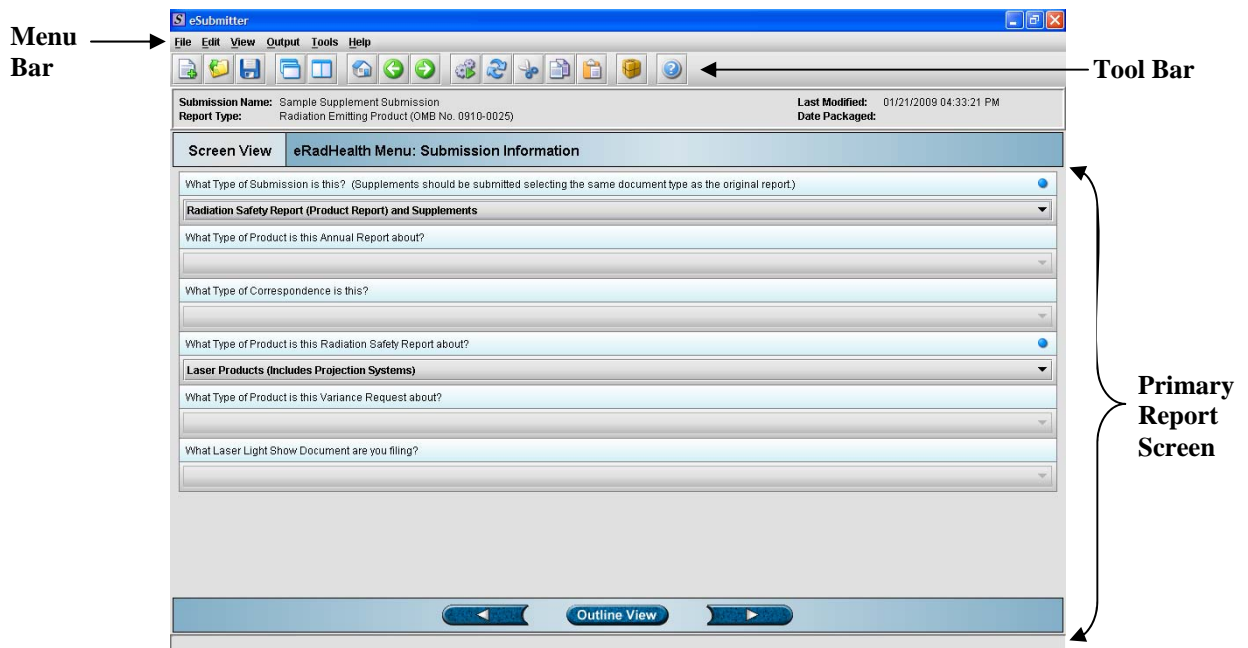
## Subsection 3.1: Application Window

### Layouts

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

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

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



### Parts of the Primary Work Area

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

## Subsection 3.1: Application Window

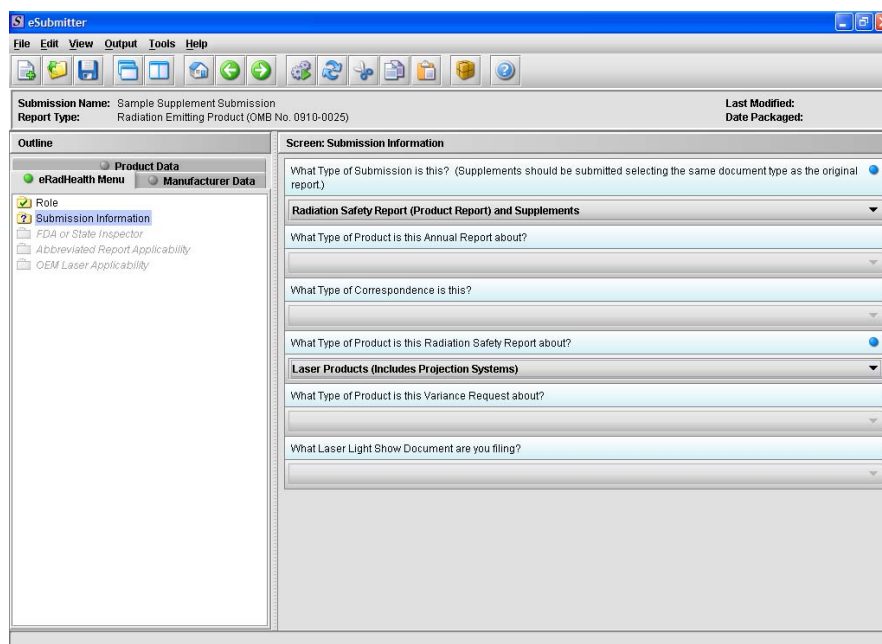
### Header Area

Displays the following general information about the open submission:

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

### Outline Area/View

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



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

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

## Subsection 3.1: Application Window

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

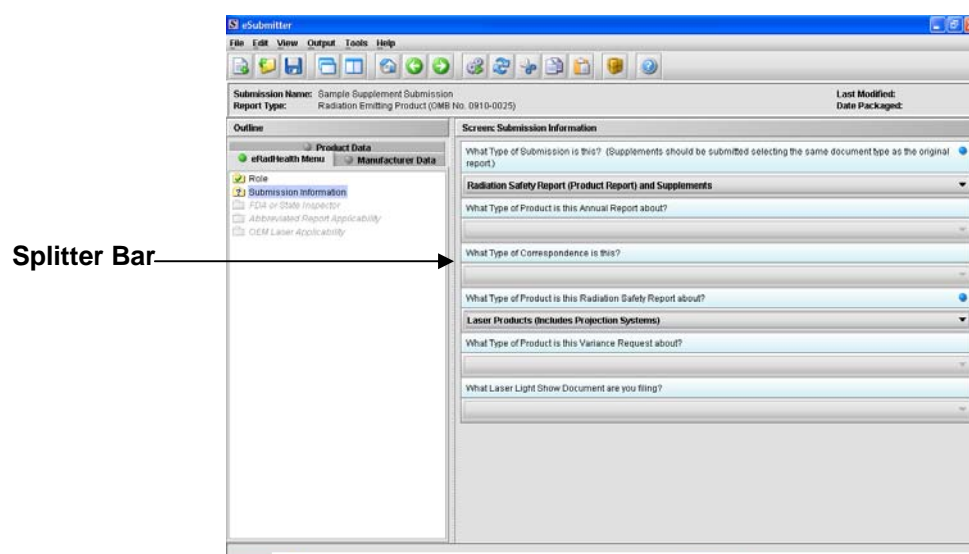
### Screen Area/View

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

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

### Splitter Bar

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



## Subsection 3.2: Toolbar







### Introduction












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

**Note:** The screens and information that are accessed through the icons can also be accessed using the following menus: **File**, **Edit**, **View**, and **Help**. However, you must access information for **Output** and **Tools** (with the exception of *Package Files for Submission*) through the actual menus. For information relating to output and tools functions, refer to pages 42 and 43 respectively.

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

Tool	Function
	<b>New</b> – Displays the <i>New Template Dialog</i> box, which allows a new (empty) template to be created.
	<b>Open</b> – Displays the <i>Open Existing Template Dialog</i> box, which allows an existing template to be selected and opened.
	<b>Save</b> – Saves any changes within the open template to permanent storage (e.g., to the disk).
	<b>Simple Layout</b> – 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.
	<b>Expert Layout</b> – Selects the expert layout, which contains the overall outline and current data entry screen side-by-side.
	<b>Home</b> – Takes you to the home screen.

## Subsection 3.2: Toolbar

	<b>Previous</b> – Navigates to the previous screen.
	<b>Next</b> – Navigates to the next screen.
	<b>Process Screen Changes</b> – Processes your changes to screens without saving the template 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.
	<b>Screen Undo</b> – Undoes most recent changes made.
	<b>Cut</b> – Cuts text.
	<b>Copy</b> – Copies text.
	<b>Paste</b> – Pastes text.
	<b>Package Files for Submission</b> – Packages your submission to send to FDA after you have completely answered all required questions. For complete information, see <i>Packaging Submission Files</i> on page 90.
	<b>Help Contents</b> – 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 85.



**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.

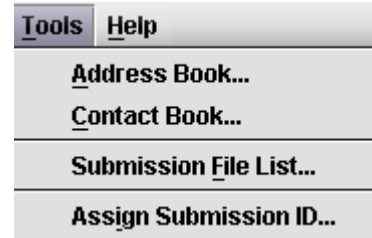
### Output Menu Commands

Each command on the Output menu is described below.

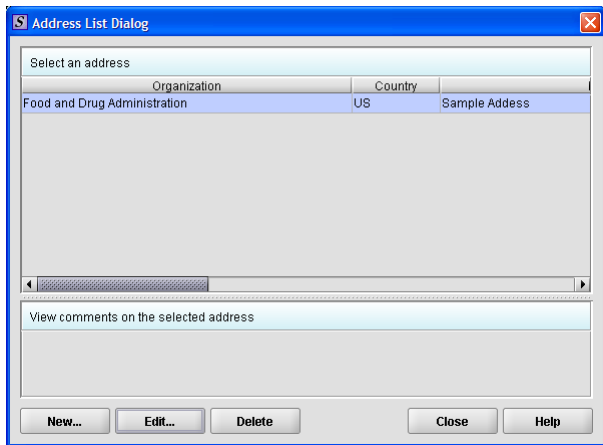
Tool	Function
<b>Missing Data Report</b>	Provides a list of required questions that you have not yet answered. The list is provided in Rich Text format. You can save the report file at any time. However, you will not be able to package a submission file to submit to FDA until there is no missing data. For complete information, see <i>Subsection 4.4: Completing a Submission</i> on page 85.
<b>Blank Report Form</b>	Views/prints a blank submission form in Rich Text.
<b>Submission Report</b>	Views/prints out the submission report with your entries in Rich Text.
<b>Submittal Letter</b>	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.
<b>Package Files for Submission</b>	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 <i>Subsection 4.4: Completing a Submission</i> on page 85.

## Subsection 3.4: Menu Bar - Tools

**Introduction** Each command on the Tools Menu is described below:



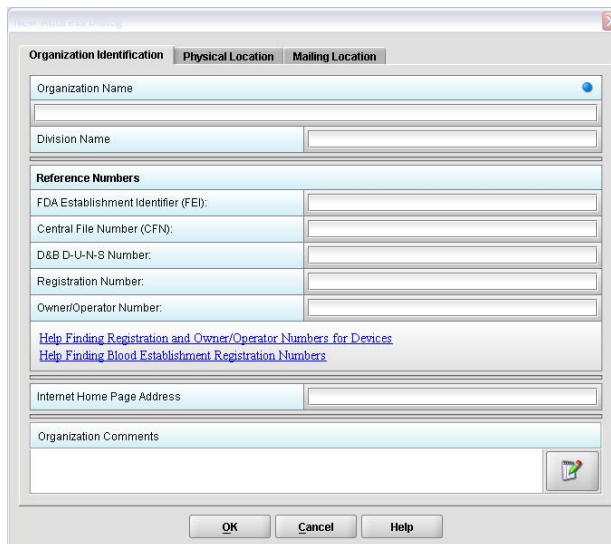
Tools	Function
<p><b>Address Book</b></p>	<p>Displays the <i>Address List Dialog</i> box, which provides the ability to maintain the addresses of the pertinent manufacturing and corporate facilities associated with your reports.</p> <p>You only need to enter each organization name and address once into the Address Book, then select the appropriate entry in response to each question. If the mailing address is the same as the physical address, the physical address can be copied into the mailing address fields. If they are similar but not exactly the same, it can be copied, and then edited. The Address Book will always be accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries.</p> <p>The <i>Address List Dialog</i> box contains a list of all the available organizations and a comments area for viewing the comments on the selected establishment. In addition, if you scroll across the address list, you'll see fields containing basic identifier information about each organization.</p> <p>The options (<b>New</b>, <b>Edit</b>, <b>Delete</b>, <b>Close</b>, and, <b>Help</b>) in this dialog box are described below:</p>



<b>New</b>	Displays the <i>New Address Dialog</i> box, which allows a new
------------	--

## Subsection 3.4: Menu Bar -Tools

organization to be created. Below is an example. Enter information in the fields to identify a particular organization.

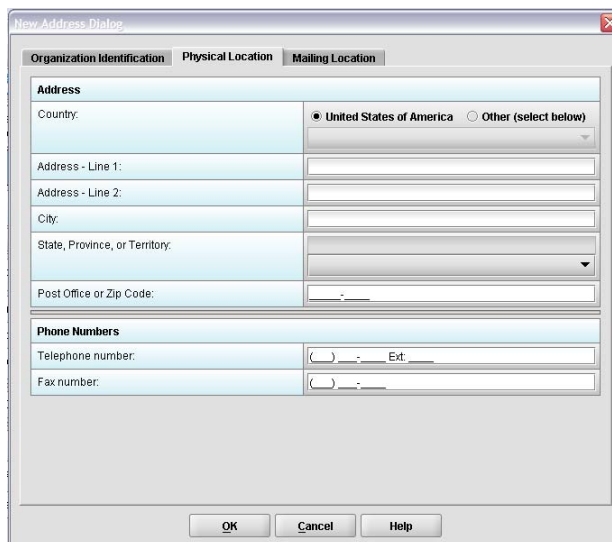


The screenshot shows the 'New Organization Dialog' window with the 'Organization Identification' tab selected. The dialog has three tabs: 'Organization Identification', 'Physical Location', and 'Mailing Location'. The 'Organization Identification' tab contains the following fields:

- Organization Name
- Division Name
- Reference Numbers**
  - FDA Establishment Identifier (FEI):
  - Central File Number (CFN):
  - D&B D-U-N-S Number:
  - Registration Number:
  - Owner/Operator Number:
- Internet Home Page Address
- Organization Comments

At the bottom of the dialog are 'OK', 'Cancel', and 'Help' buttons. There are also two blue hyperlinks below the Reference Numbers section: [Help Finding Registration and Owner/Operator Numbers for Devices](#) and [Help Finding Blood Establishment Registration Numbers](#).

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



The screenshot shows the 'New Address Dialog' window with the 'Physical Location' tab selected. The dialog has three tabs: 'Organization Identification', 'Physical Location', and 'Mailing Location'. The 'Physical Location' tab contains the following fields:

- Address**
  - Country:  United States of America  Other (select below)
  - Address - Line 1:
  - Address - Line 2:
  - City:
  - State, Province, or Territory:
  - Post Office or Zip Code:
- Phone Numbers**
  - Telephone number: ( ) - - Ext. -
  - Fax number: ( ) - -

At the bottom of the dialog are 'OK', 'Cancel', and 'Help' buttons.

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



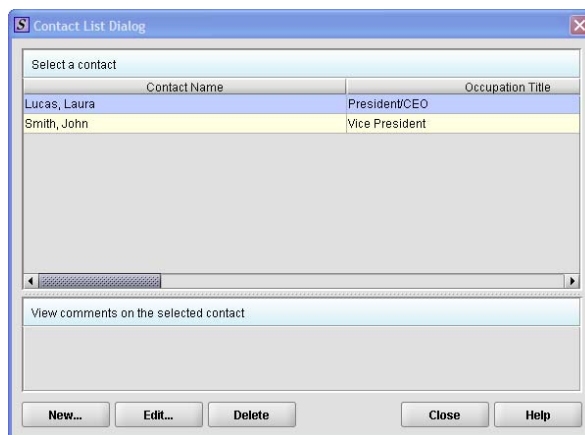
⇒ Click **Copy Address** if the mailing location is the same as the physical location of the organization. The information is automatically copied into the address fields (as shown above). However, if the mailing location differs drastically from the physical location, you must manually enter the information.

⇒ When you are finished with the addresses, click **OK** to save your edits. Click **Cancel** to ignore all edits or **Help** to see help text. You return to the *Address List Dialog* box.

<b>Edit</b>	Displays the <i>Edit Address Dialog</i> box, which allows the selected establishment information to be changed. (You enter information in this dialog box in the same manner as the <i>New Establishment Dialog</i> box.)
<b>Delete</b>	Deletes the selected address from the list.
<b>Close</b>	Closes the dialog box.
<b>Help</b>	Displays the help window with text.

## Subsection 3.4: Menu Bar -Tools

Tools	Function
<p><b>Contact Book</b></p>	<p>Displays the <i>Contact List Dialog</i> 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.</p> <p>The <i>Contact List Dialog</i> 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.</p> <p>The options provided in this dialog box are described below:</p>



<b>New</b>	Displays the <i>New Contact Dialog</i> box, which allows a new contact to be created.
<b>Edit</b>	Displays the <i>Edit Contact Dialog</i> box, which allows the selected contact information to be changed.
<b>Delete</b>	Deletes the selected contact from the list.
<b>Close</b>	Closes the dialog box.
<b>Help</b>	Displays the help window with text.

Tools	Function
<p><b>Submission File List</b></p>	<p>Displays the <i>Master File Attachment Dialog</i> box, which allows you to manage the file information to be attached for use across questions in the submission.</p> <div data-bbox="591 438 1357 1045" data-label="Image"> </div> <p>Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). If you did not set your file viewer under User Preferences, the first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 21.</p> <p><b>Note:</b> The file list is specific to the submission that is currently open, thus not retained nor accessible for future reports.</p> <p>The <i>Master File Attachment Dialog</i> box manages the file attachment information related to the open submission. The dialog box contains a list of all the attached files that are currently available, an area for general information on the selected file, and options for managing the list. The file list displays the following for each:</p> <ul style="list-style-type: none"> <li>• Descriptive title</li> <li>• Physical file name</li> <li>• Number of questions that currently reference the file as an attachment</li> <li>• File date</li> <li>• File size</li> </ul>

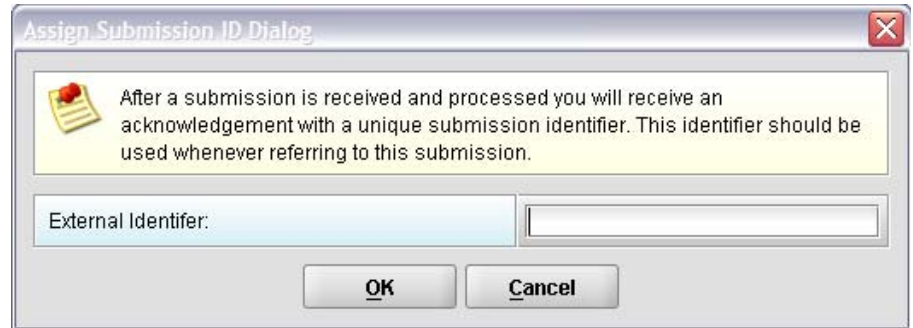
## Subsection 3.4: Menu Bar -Tools

	<ul style="list-style-type: none"> <li>• Path to the file location</li> </ul> <p>The options provided in the dialog box are described below:</p>
--	--

<b>Add a New File</b>	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 <i>How to Attach a File to an Attachment Question Type</i> , beginning on page 60.
<b>View/ Manage File List</b>	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.
<b>View</b>	Displays the selected file within the specified PDF viewer.
<b>Edit</b>	Displays the <i>Edit File Dialog</i> box, which allows the selected file title and general description to be changed.
<b>Delete</b>	Deletes the selected file from the list.
<b>Close w/ Changes</b>	Closes the dialog box and saves the changes made to the <i>Master File Attachment</i> list.

<b>Tools</b>	<b>Function</b>
<b>Assign Submission ID</b>	<p>Allows you to enter an FDA-related identifier to a submission. After you have sent the submission to the FDA for processing and if you have received a unique identifier, you may store that FDA assigned identifier in the submission for tracking purposes. For complete information on preparing a submission, see page 50.</p> <p><b>To enter a Report ID:</b></p> <p>⇒ Select <b>Assign Submission ID</b> from Tools on the Menu bar. You see the <i>Assign Submission ID dialog</i> box (see below).</p> <p>⇒ Enter the unique identifier assigned by FDA.</p>

⇒ If you are satisfied with your entry, click **OK**. Or, click **Cancel** to close the dialog box without making any changes.



# Section 4: Preparing a Submission

## Contents

This section contains the following topics:

<b>Topic</b>	<b>See Page</b>
Entering Submission Information	51
Question Types	52
▶ Address and Contact Information	53
▶ Option Lists	56
▶ File Attachments	59
▶ Guidance Documents	65
▶ Text Fields and Messages	68
▶ Product Codes	70
▶ Standards	76
▶ Sections as Tables	78
Relationships Across Screens	81
Saving Submission Entries or Changes	84
Completing a Submission	85

## 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.

### Entering Responses into the Submission

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

	Action	Graphic
1.	The eSubmitter application must be open on your computer desktop, and a submission must be open. If the application and a submission are not open, see the instructions beginning on page 8.	
2.	Navigate through the submission as follows: <ul style="list-style-type: none"><li>• If you are in the simple layout, use the buttons on the navigation bar to advance to next/return to previous screen.</li><li>• 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.</li></ul>	

## Subsection 4.1: Entering Submission Information

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

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

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

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



## Subsection 4.2.1: Question Types – Address and Contact Information

<p><b>Address</b></p>	<p>This question type requires that you enter the address and phone numbers of your organization. You enter the information in text fields and make selections using drop-down menus and clicking option buttons. An example is shown below. Other types of address questions are <b>Contact</b> and <b>Multi-Part Address</b>, which will be discussed below.</p> <div data-bbox="570 657 1357 1167" data-label="Form"> </div>
<p><b>Contact (Simple)</b></p>	<p>This question type requires that you type contact information (first name, last name, etc.) in text fields. Entries may or may not be required. The figure below shows an example of a simple contact question with the first name, last name, and email address as required fields (as indicated by the blue dots).</p> <div data-bbox="570 1417 1414 1730" data-label="Form"> </div>
<p><b>Contact (Multi-Part)</b></p>	<p>This question type contains multiple sections that you need to complete (indicated by the tabs: Contact Information, Establishment Identification, Physical Location, and Mailing</p>

## Subsection 4.2.1: Question Types – Address and Contact Information

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

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

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

The screenshot shows a form with four tabs: "Contact Identification", "Establishment Identification", "Physical Location", and "Mailing Location". An arrow labeled "Tabs" points to the right side of the tab bar. The "Contact Identification" tab is selected and active. Below the tabs, there is a section titled "Contact" containing six input fields: "Title (Mr., Ms., Dr.)", "First/Given Name", "Middle Name", "Last Name", "Occupation Title", and "Email Address". Each field has a small blue circular icon to its right, which is the "Copy from Contact Book" icon.

### Copy Information from Contact Book into Question

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

#### Action

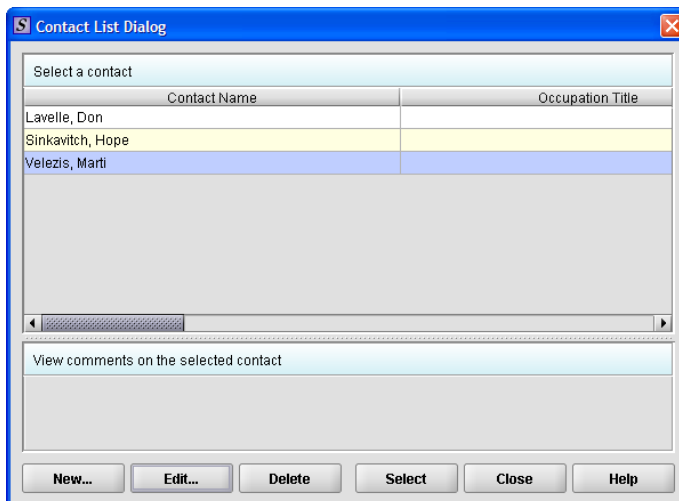
#### Graphic

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

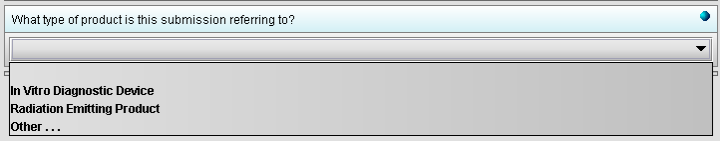

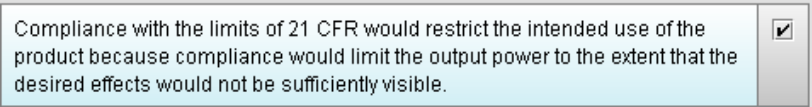
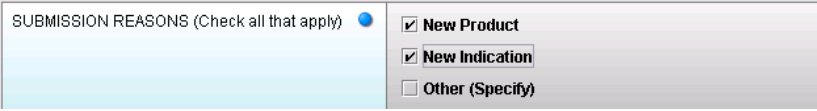
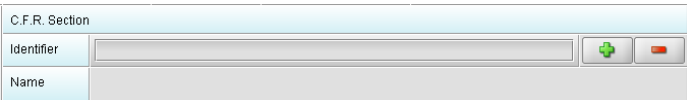
### Contact List Dialog Box



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 53.



## Subsection 4.2.2: Question Types – Option Lists

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

## Subsection 4.2.2: Question Types – Option Lists

### Access the List of Available Options

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

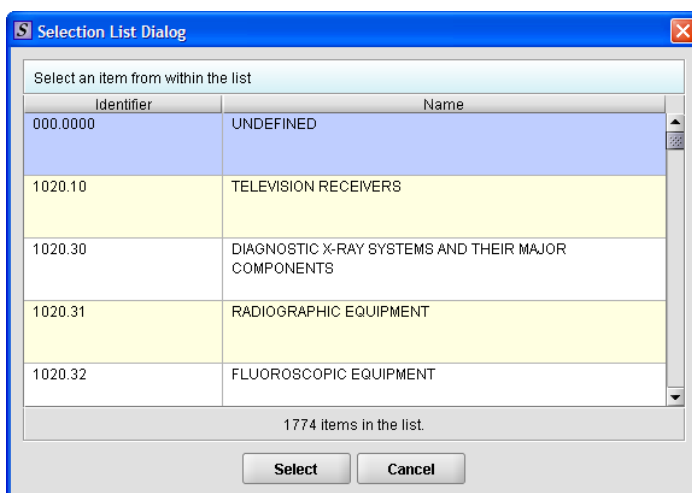
#### Action

#### Graphic

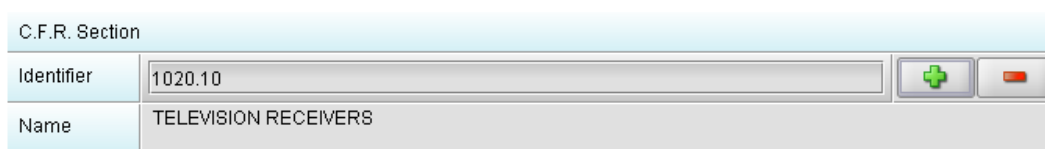
1. Click the **Select Item** icon. A *Selection List Dialog* box is displayed (as shown below).



### 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.





## Subsection 4.2.2: Question Types – Option Lists

- Repeat steps 1 through 3 to make another selection.

<b>Table</b>	<p>This question type allows you to select from a list or add text items that are then placed in a table. Below is an example.</p> 
--------------	---

### 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 <b>Add</b> icon.	
2.	You will be prompted to either select from a list of options or enter a response into a text field.	
3.	If you wish to change your response, select (highlight) the option in the table and click the <b>delete</b> 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

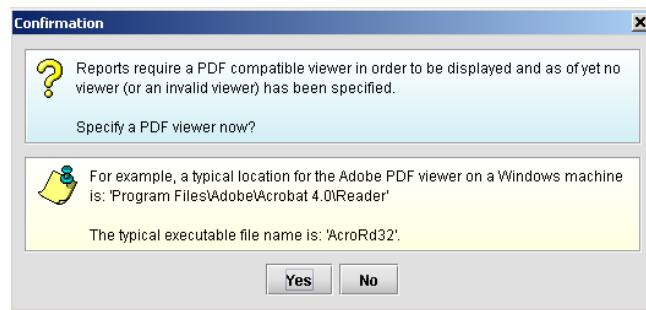
### File Attachment

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.

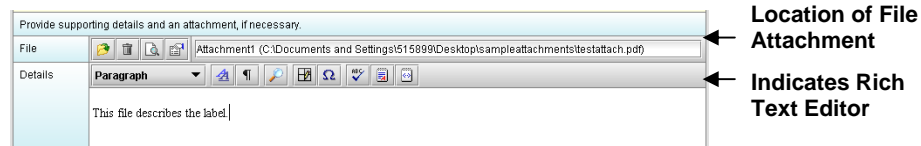
Note that the question itself may be restricted to only allow certain file types to be attached (e.g., PDF only or a combination, such as PDF and/or Excel file types only).

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.



## Subsection 4.2.3: Question Types – File Attachments

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### 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.

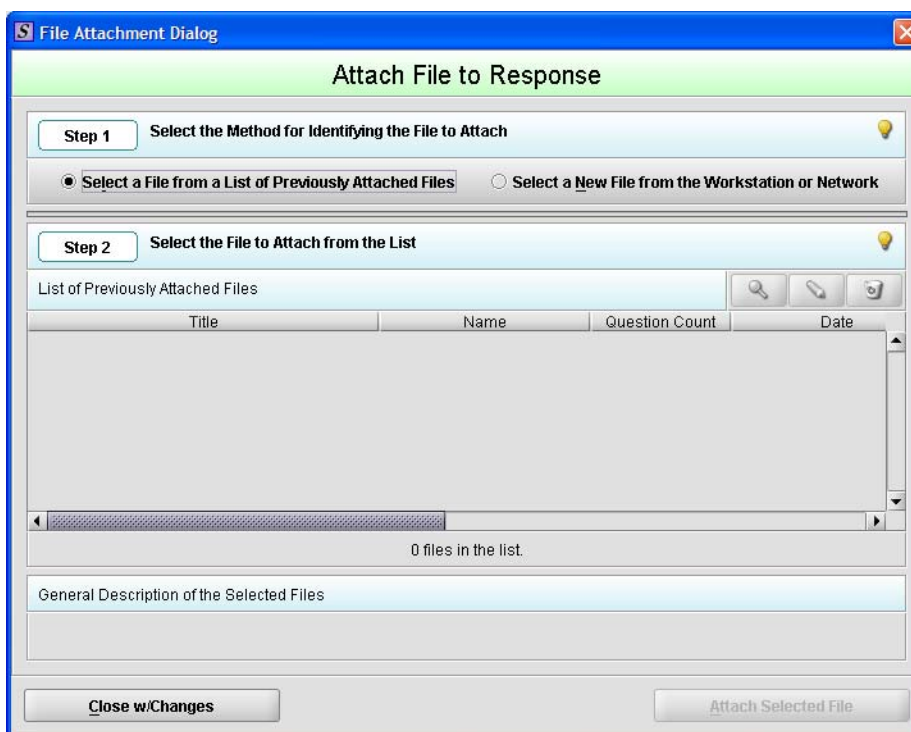
#### Action

#### 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



## Subsection 4.2.3: Question Types – File Attachments

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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”.

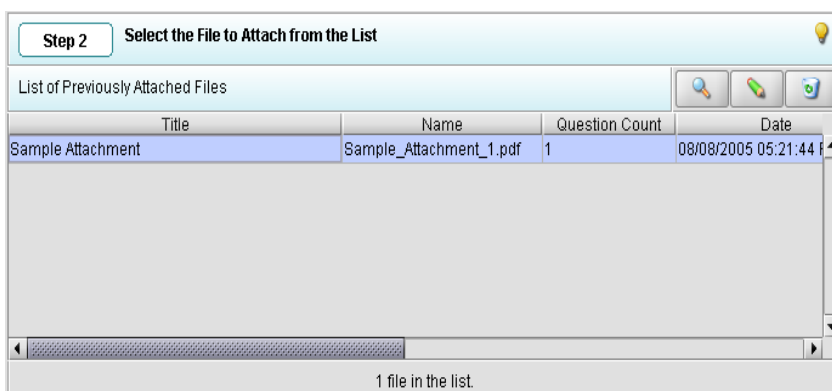
---

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

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

---

### Select a File from a List of Previously Attached Files



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

**Attach Selected File**

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

---

## Subsection 4.2.3: Question Types – File Attachments

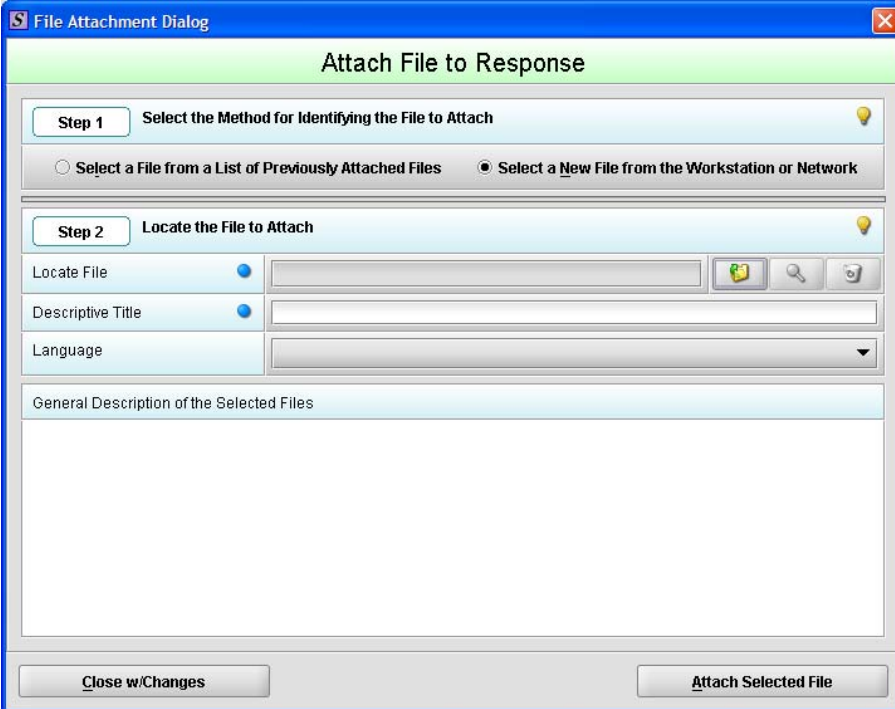
---

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).
- 

**Select a New File from the Workstation or Network**



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



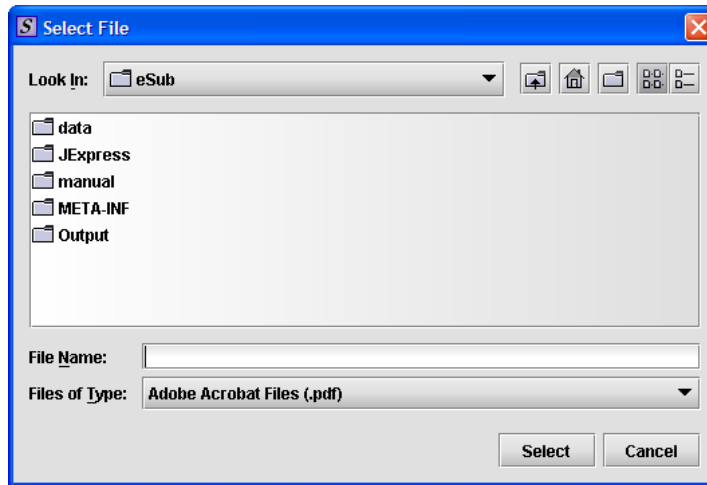
You will see a *Select File* dialog box as shown below.

---

## Subsection 4.2.3: Question Types – File Attachments

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### Select File Dialog Box



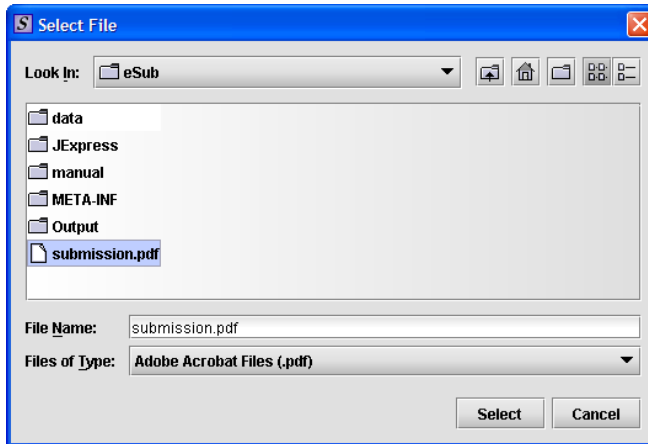
- 
8. Verify that the correct file type is selected in the **Files of Type** drop down located below the **File Name** field. Only those files of the type chosen will appear in the display pane for you to select. The **Files of Type** is defaulted to **Adobe Acrobat Files (.pdf)**.

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

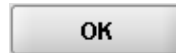
- 
9. Click the **Look In** drop-down menu to locate the drive, such as Local Disk (C:), or folder where the file you wish to attach is stored.
  10. When you locate the desired file, click to select it (highlight). The name of the file appears in **File Name** (as shown below).
-

## Subsection 4.2.3: Question Types – File Attachments

### Select File Dialog Box – File Selected



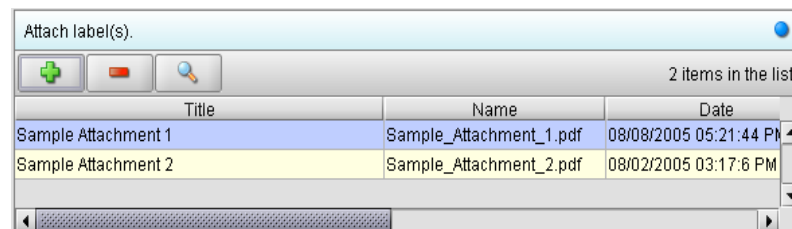
11. Click **Select**. The *Select File* dialog box closes, and you return to the *New File* dialog box.
12. Enter a title in **Descriptive title** (required entry) and a description in **General description**, if desired.
13. Click **OK**. You return to the *File Attachment Dialog* box. The PDF that you just added is automatically displayed in the fields in Step 2.
14. Click **Attach Selected File(s)**. You see the path (location) of the file selected appear in the file attachment question.



### Multiple File Attachments

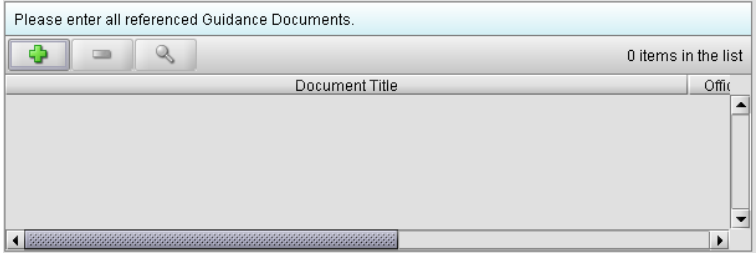
This question type allows you to attach multiple files as a response. Below is an example of an attachment question with a file attachment included. In the image below, the green plus sign is still enabled after attaching a file, indicating that additional files may be attached as the response.

To attach multiple PDF files to an attachment question, follow the same instructions listed under *How to Attach a File to an Attachment Question Type* beginning on page 60.



Scroll Bar to view additional details on files

## Subsection 4.2.4: Question Types – Guidance Documents

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

To select a guidance document, follow the instructions below.

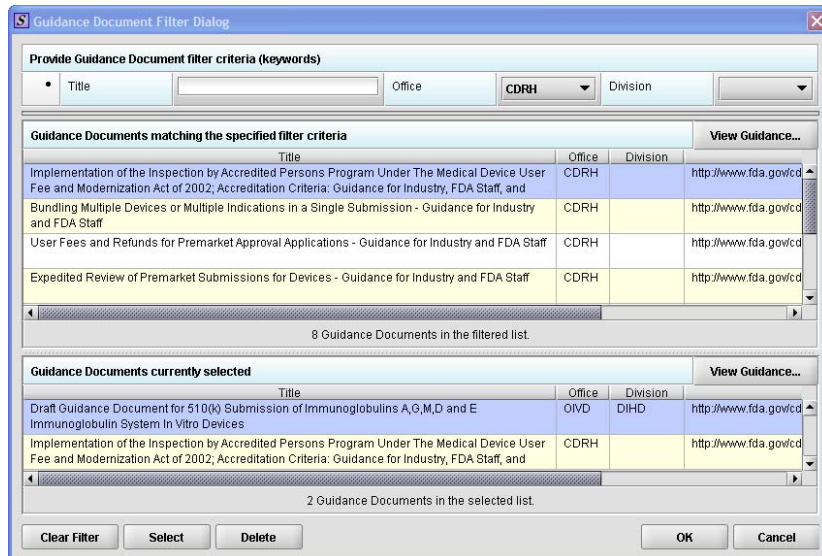
#### Action

#### Graphic

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



### Guidance Document Filter Dialog Box



Title	Office	Division	URL
Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria. Guidance for Industry, FDA Staff, and	CDRH		http://www.fda.gov/cd
Bundling Multiple Devices or Multiple Indications in a Single Submission - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cd
User Fees and Refunds for Premarket Approval Applications - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cd
Expedited Review of Premarket Submissions for Devices - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cd

Title	Office	Division	URL
Draft Guidance Document for 510(k) Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In Vitro Devices	OVD	DIHD	http://www.fda.gov/cd
Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria. Guidance for Industry, FDA Staff, and	CDRH		http://www.fda.gov/cd

## Subsection 4.2.4: Question Types – Guidance Documents

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

Clear Filter

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

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

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

View Guidance...

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

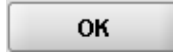
- Click to select (highlight) a particular guidance document.
- Click **Select**. The selected document appears in **Guidance Documents currently selected** area of the screen.
- Repeat the above two items for each desired guidance document.
- Click **Delete** to remove a guidance document from your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

Select

Delete

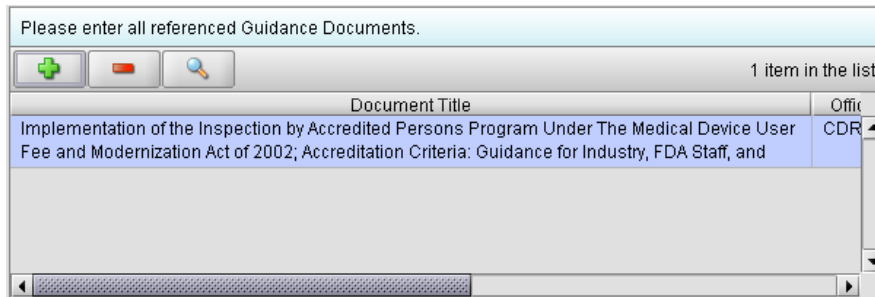
## Subsection 4.2.4: Question Types – Guidance Documents

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



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

### Guidance Document Containing a Response




Please enter all referenced Guidance Documents.

1 item in the list


Document Title	Office
Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and	CDR

The screenshot shows a software window with a title bar that reads "Please enter all referenced Guidance Documents." Below the title bar are three icons: a green plus sign, a red minus sign, and a magnifying glass. To the right of these icons, it says "1 item in the list". Below this is a table with two columns: "Document Title" and "Office". The table contains one row with the following text: "Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and" in the "Document Title" column, and "CDR" in the "Office" column. The table has a scroll bar on the right side.

## Subsection 4.2.5: Question Types – Text Fields and Messages

<p><b>Memo (Multi Line Text)</b></p>	<p>This question type provides an area for you to enter several lines of text (as shown below).</p> <div data-bbox="630 512 1414 684" style="border: 1px solid gray; padding: 5px;"> <p>Enter your 510(k) Summary or Statement.</p> </div> <p>The question may contain a Rich Text Editor which allows you to format what you type (bold, underline), run spell check, or insert a table. The tool bar for the Rich Text Editor will appear after you click in the text area to begin typing.</p> <div data-bbox="630 894 1414 1031" style="border: 1px solid gray; padding: 5px;"> <p>Paragraph</p>  </div>
--	--

<p><b>Text, Single Line</b></p>	<p>This question type allows you to type in text as a response. Below shows an example of a text question.</p> <div data-bbox="573 1247 1398 1287" style="border: 1px solid gray; padding: 5px;"> <p>Provide the Accession Number of the report for which this is a supplement:</p> <input style="width: 80px;" type="text"/> </div>
---	--

<p><b>Message</b></p>	<p>This question type provides information to you as you complete a submission. You may see several different types of messages as you progress through your submission. Different examples of the message types are listed below:</p> <ul style="list-style-type: none"> <li>• <b>Information Message</b></li> </ul> <div data-bbox="626 1644 1414 1703" style="border: 1px solid gray; padding: 5px; background-color: #e0ffe0;">  <p>Select the CDRH Recognized Standard from the available list.</p> </div> <ul style="list-style-type: none"> <li>• <b>Error Message</b></li> </ul>
-----------------------	---



## Subsection 4.2.5: Question Types – Text Fields and Messages

The screenshot displays a vertical list of message types and their corresponding visual representations:







- Note Message:** A pink message box with a red 'STOP' icon. The text reads: "Unfortunately, this software currently only supports submissions for in vitro diagnostic devices, radiation emitting products, and medical device adverse event reporting. For all other submissions, please check back at a later date for information on additional submissions that will be supported by this software. Please email any questions or comments to the CeSub team at: cdrhesub@cdhrh.fda.gov. Be sure to include your name, company name and contact information in the email. Thank you again for using our electronic product reporting software."
- Confirmation Message:** A yellow message box with a notepad icon. The text reads: "Contains Information on the Applicable Contacts"
- Warning Message:** A light blue message box with a question mark icon. The text reads: "Save the following changes before closing the report template?"
- Missing Data Message:** A pink message box with a warning triangle icon. The text reads: "Any changes made will be lost if they are not saved. Selecting the Cancel button will prevent the operation from continuing (i.e., closing the report template)."

Below the messages is a screenshot of a "Message Dialog" window. The dialog has a title bar with a close button (X). The main area contains a label "Select an option" and two radio button options:

- I would like to add another Product
- I am finished entering Product(s) and I would like to move to the next screen


At the bottom of the dialog are two buttons: "OK" and "Cancel".

## Subsection 4.2.6: Question Types – Product Codes

<b>Product Code (Single)</b>	<p>This question type allows you to search for and then identify the product code that is assigned to your product or device. If applicable, you are able to search for the device class, device panel, and particular CFR section. The response to this question is for a single product code. Below is an example of a product code question.</p> <p><b>Note:</b> The Product Code is specific to those filing with the Center for Devices and Radiological Health.</p> <div style="border: 1px solid gray; padding: 5px;"> <p>Choose the product code for this submission.</p> <table border="1"> <tr> <td style="width: 150px;">Product Code</td> <td><input type="text"/></td> <td style="text-align: right;"></td> <td style="text-align: right;"></td> </tr> <tr> <td>Product Code Name</td> <td colspan="3"></td> </tr> <tr> <td>Device Class</td> <td colspan="3"></td> </tr> <tr> <td>Classification Panel</td> <td colspan="3"></td> </tr> <tr> <td>C.F.R. Section</td> <td colspan="3"></td> </tr> </table> <p>Add any other product codes that are applicable to this submission.</p> </div>	Product Code	<input type="text"/>			Product Code Name				Device Class				Classification Panel				C.F.R. Section			
Product Code	<input type="text"/>																				
Product Code Name																					
Device Class																					
Classification Panel																					
C.F.R. Section																					


### 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 <b>Select Item</b> icon. A <i>Product Code Filter Dialog</i> box is displayed.	

## Subsection 4.2.6: Question Types – Product Codes

### Product Code Filter Dialog Box

Product Code Filter Dialog

Provide Product Code filter criteria



- Product Code Name (keyword search)
- Device Class
- Classification Panel
- C.F.R. Section
  - Identifier
  - Name

Matching Product Codes


Product Code	Product Code Name	Device Class	Cl
--------------	-------------------	--------------	----



0 Product Codes in the list.



Clear Filter Select Cancel

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

## Subsection 4.2.6: Question Types – Product Codes


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).

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

<b>Product Codes (Multiple)</b>	This question type allows you to identify other product codes applicable to the submission. Below is an example of a multiple product code question.								
	  2 items in the list								
	<table border="1"> <thead> <tr> <th>Product Code</th> <th>Product Code Name</th> <th>Device Cl</th> </tr> </thead> <tbody> <tr> <td>REJ</td> <td>LASER TOY/NOVELTY PRODUCT</td> <td>UNCLASSIF ▲</td> </tr> <tr> <td>LKW</td> <td>LASER, NEUROSURGICAL</td> <td>CLASS III</td> </tr> </tbody> </table>	Product Code	Product Code Name	Device Cl	REJ	LASER TOY/NOVELTY PRODUCT	UNCLASSIF ▲	LKW	LASER, NEUROSURGICAL
Product Code	Product Code Name	Device Cl							
REJ	LASER TOY/NOVELTY PRODUCT	UNCLASSIF ▲							
LKW	LASER, NEUROSURGICAL	CLASS III							

### Add Product Codes

To add product codes, follow the instructions below:

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

## Subsection 4.2.6: Question Types – Product Codes

### Product Code Filter Dialog Box

Product Code Filter Dialog

Provide Product Code filter criteria (keywords)

- Product Code  Product Code Name
- Device Class  Classification Panel
- C.F.R. Section
  - Identifier
  - Name

Product Codes matching the specified filter criteria

Product Code	Product Code Name	Device Class	Classification
0 Product Codes in the filtered list.			

Product Codes currently selected

Product Code	Product Code Name	Device Class	Classification
0 Product Codes in the selected list.			

Clear Filter Select Delete OK Cancel

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



### Enter Multiple Three-Letter Codes in the Product Code Question

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

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

#### Action

#### Graphic

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

## Subsection 4.2.6: Question Types – Product Codes

Product Codes matching the specified filter criteria			
Product Code	Product Code Name	Device Class	Classification
BRT	RESTRAINT, PATIENT, CONDUCTIVE	CLASS I	GENERAL HOS
BRW	PROTECTOR, DENTAL	CLASS I	ANESTHESIO

2168 Product Codes in the filtered list.

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



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

- 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

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

## Subsection 4.2.6: Question Types – Product Codes

---

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

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



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

**OR**

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

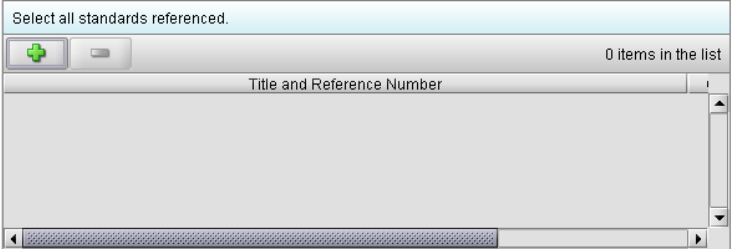


5. Click **OK** to return to the multiple product codes question, which shows your selections.



---

## Subsection 4.2.7: Question Types – Standards

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

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

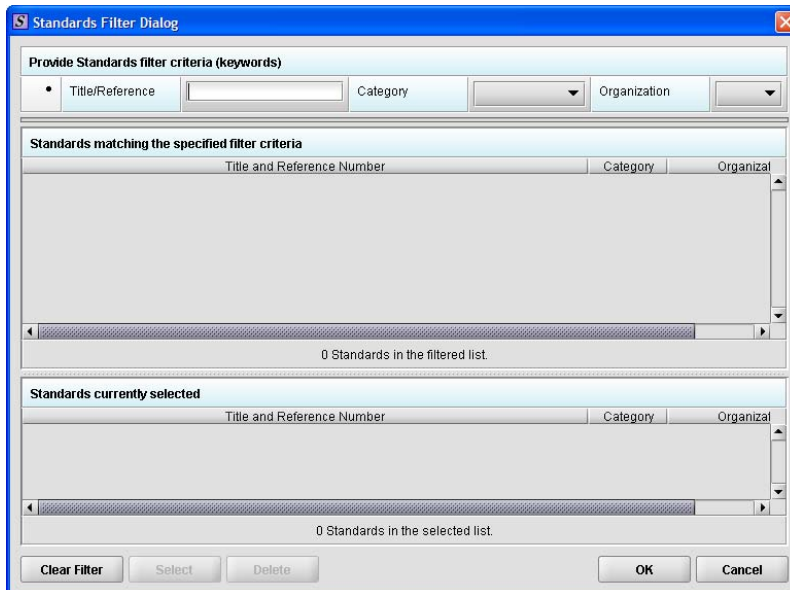
### Action

### Graphic

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



### Standard Filter Dialog Box




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



## Subsection 4.2.7: Question Types – Standards

---

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

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



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



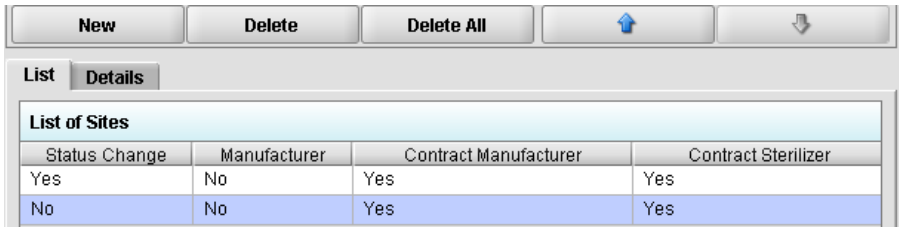
## Subsection 4.2.8: Question Types – Sections as Tables

### Sections as Tables with a Tabbed View

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

**List View**

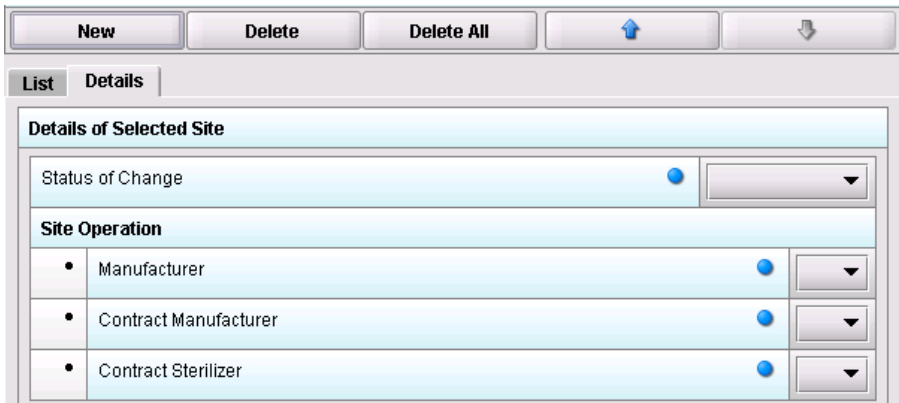
The tabbed view format is indicated by a row of buttons for **New**, **Delete**, **Delete All**, an up arrow, and a down arrow. Directly below this row of buttons is the actual table (as shown below).



Status Change	Manufacturer	Contract Manufacturer	Contract Sterilizer
Yes	No	Yes	Yes
No	No	Yes	Yes

**Details View**

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.



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.

### Sections as Tables with a Panel View

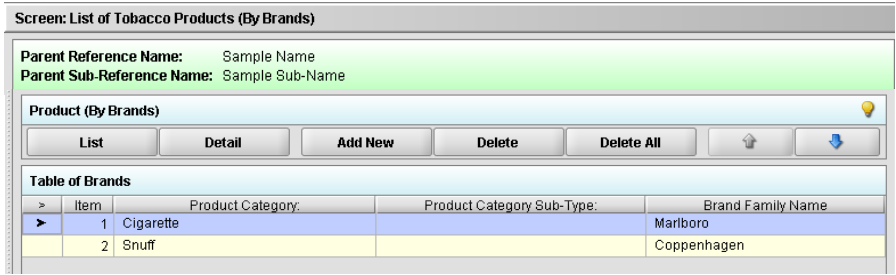
Similar to the tabbed view, in the panel view, entire sections may appear as a table, follow the instructions below:

	This format is indicated by a row of buttons for <b>Add New</b> , <b>Delete</b> ,
--	---

# Subsection 4.3: Relationships Across Screens

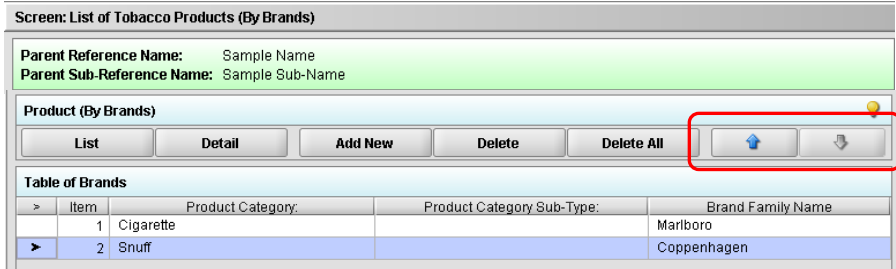
**List View**

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



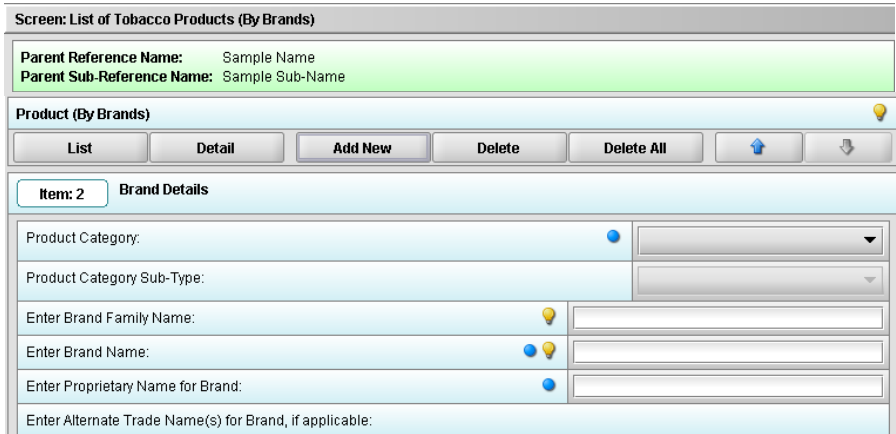
The up and down arrow, as seen below, will allow you to select a specific row when you have multiple entries. You can be sure that the appropriate row is selected as the row will be highlighted in blue and there will be an arrow in the right hand column. Please note the Item number column as this will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

# Subsection 4.3: Relationships Across Screens

**Item Number**

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.

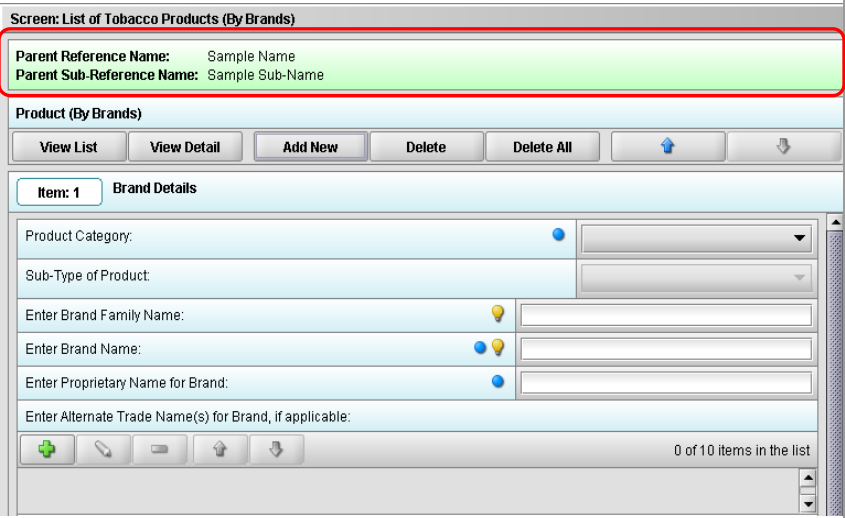
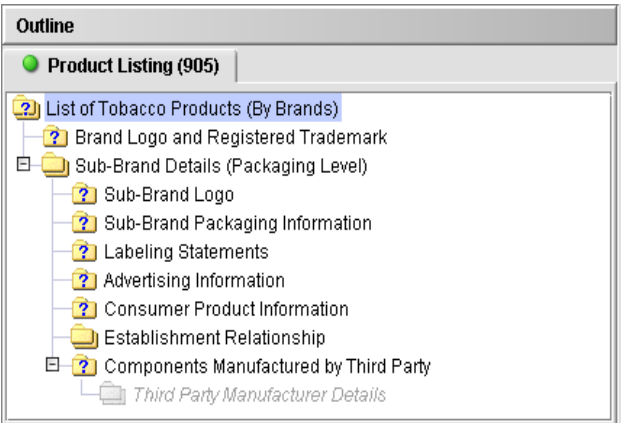
If you have added multiple entries, you will note that in the **Detail** or in the **Add New** view, the Item Number, highlighted below, will change based on the Item Number as seen in the **List** view above.

The screenshot shows a web application interface for managing tobacco products. At the top, it says "Screen: List of Tobacco Products (By Brands)". Below this, there are fields for "Parent Reference Name" (Sample Name) and "Parent Sub-Reference Name" (Sample Sub-Name). The main section is titled "Product (By Brands)" and contains a toolbar with buttons for "List", "Detail", "Add New", "Delete", "Delete All", and navigation arrows. Below the toolbar, there is a table with one row: "Item: 2 Brand Details", which is highlighted with a red rectangular box. Underneath the table, there are several form fields: "Product Category" (set to "Snuff"), "Product Category Sub-Type", "Enter Brand Family Name" (Copenhagen), "Enter Brand Name" (Copenhagen Wintergreen), "Enter Proprietary Name for Brand" (Copenhagen Wintergreen), and "Enter Alternate Trade Name(s) for Brand, if applicable".

## 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:

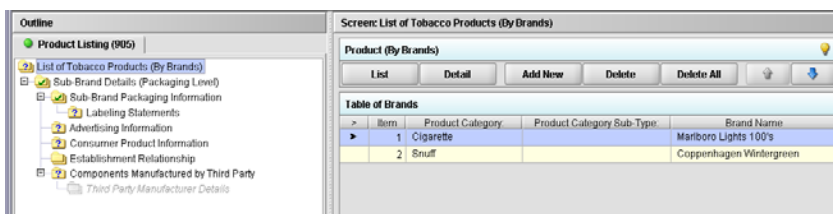
<p><b>Relationship Header</b></p>	<p>If this parent/child relationship exists, you will see a header bar on the child screens, as seen below, indicating which list item within the parent table you are currently entering data for. These child screens will be repeated for each list entry in the parent table, as necessary.</p> 
<p><b>Expert View Relationship</b></p>	<p>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.</p> 

## Subsection 4.3: Relationships Across Screens

### 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.

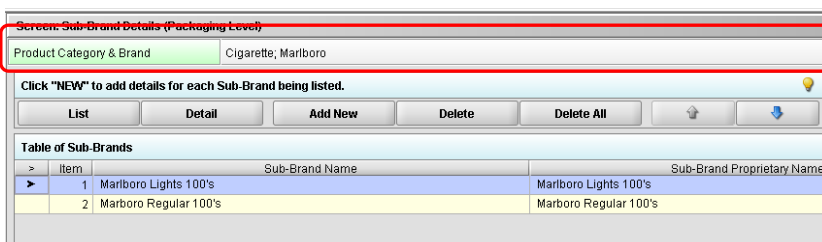
In the expert view on the left, you see the parent folder named “List of Tobacco Products (By Brands)”, below, and the parent folder’s corresponding simple screen.



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**

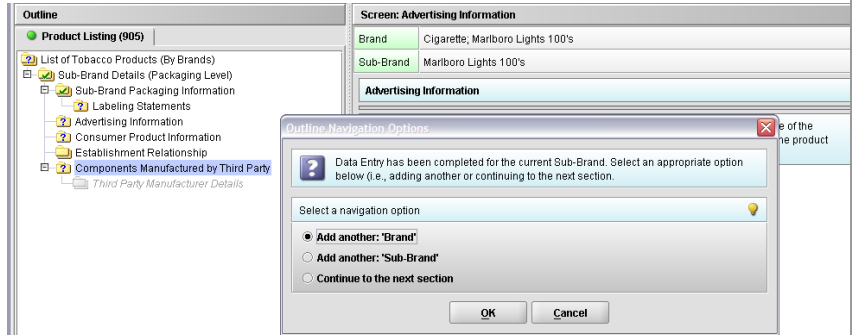
- enter a new child to the parent (e.g., the sub-brand),

**OR**

## Subsection 4.3: Relationships Across Screens

### 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 <b>File &gt; Save</b> .	
<b>OR</b>	
Click the <b>Save</b> 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 <i>Reopening an Existing Submission</i> on page 33.	
2. If you wish to close the submission, click <b>File &gt; Close</b> . The <i>Intro Screen</i> 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.

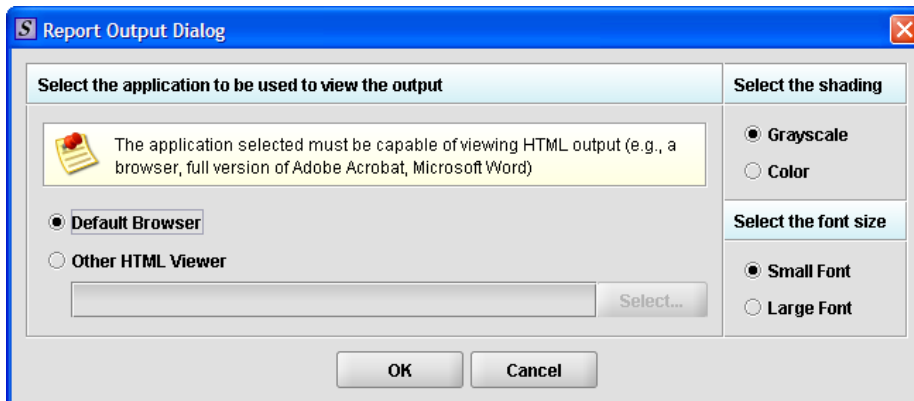
To determine if required data is missing from the submission, follow the instructions below:

### 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



## Subsection 4.4: Completing a Submission

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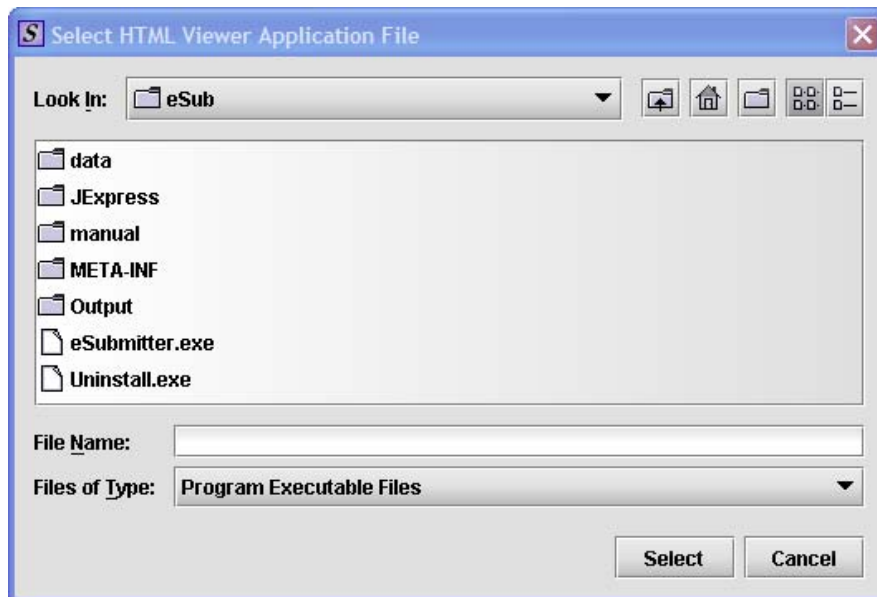
2. On this dialog box:

- 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**

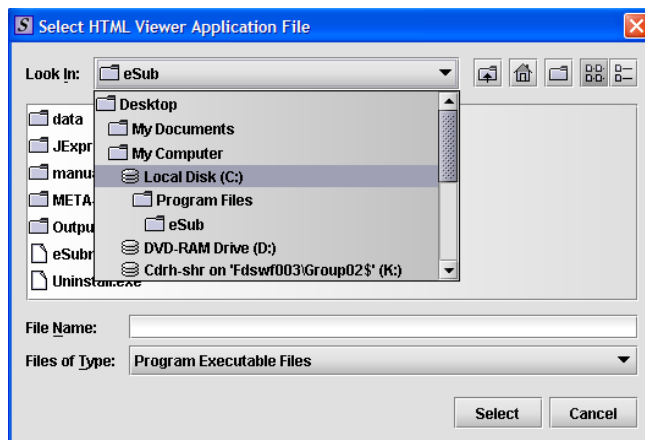


## Subsection 4.4: Completing a Submission

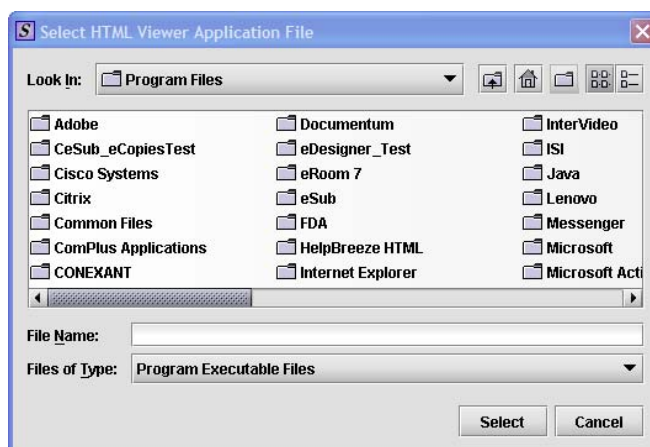
- Click in the **Look In** box to navigate to the **executable (.EXE)** of the application to view the HTML. For example, if you want to view the missing data output report in Word 2002, you would navigate using the following path:

**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):

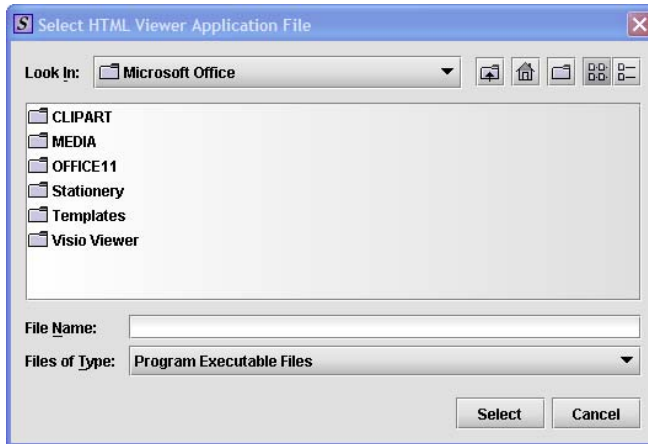


**Finding Word's Executable File (Navigation 1)**

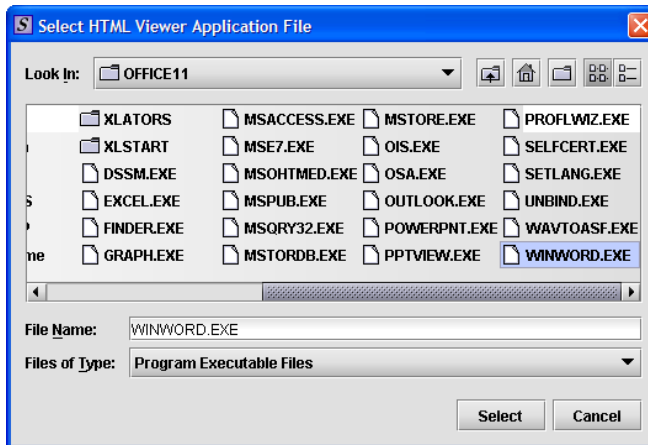


**Finding Word's Executable File (Navigation 2)**

## Subsection 4.4: Completing a Submission



Finding Word's Executable File (Navigation 3)

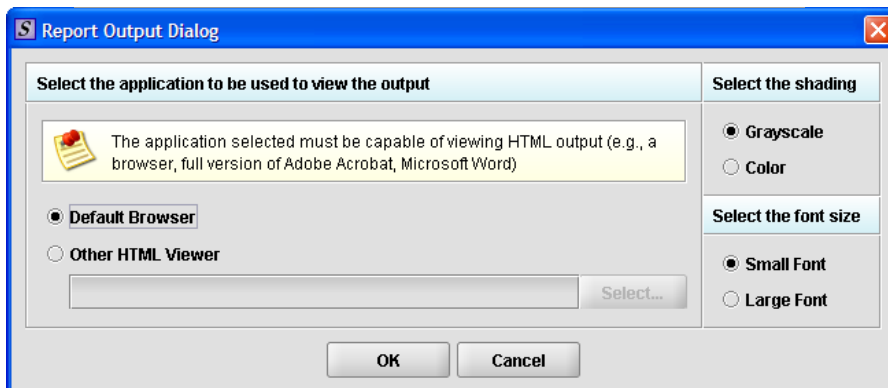


Finding Word's Executable File (Navigation 4)

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



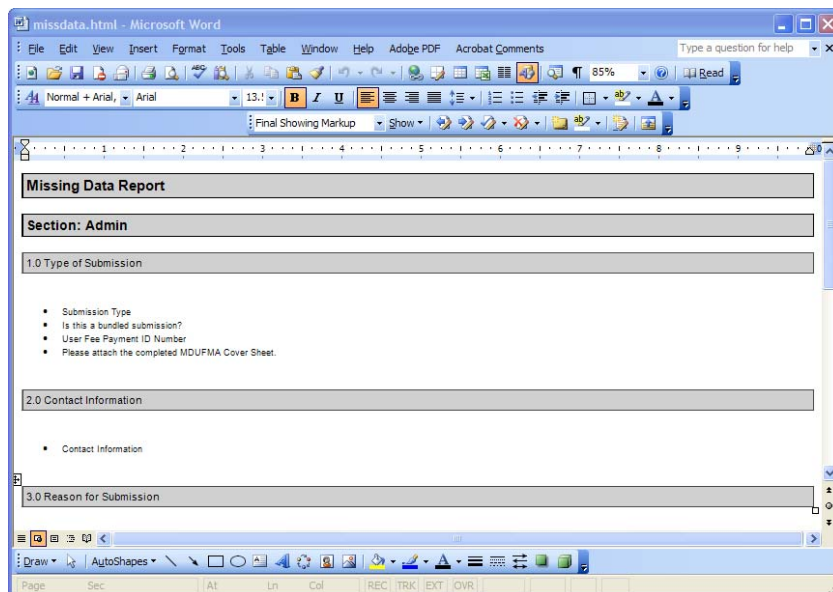
### Report Output Dialog Box



## Subsection 4.4: Completing a Submission

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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

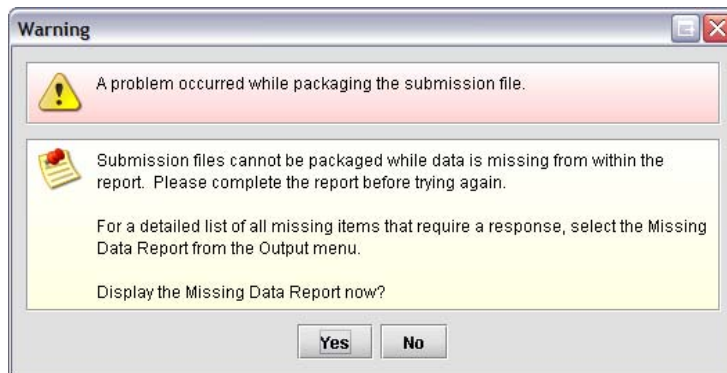
To package files for submission, follow the instructions below.

#### Action

#### Graphic

1. Click **Output > Package Files for Submission** from the menu bar.
2. If data is missing, see the warning (as shown below).

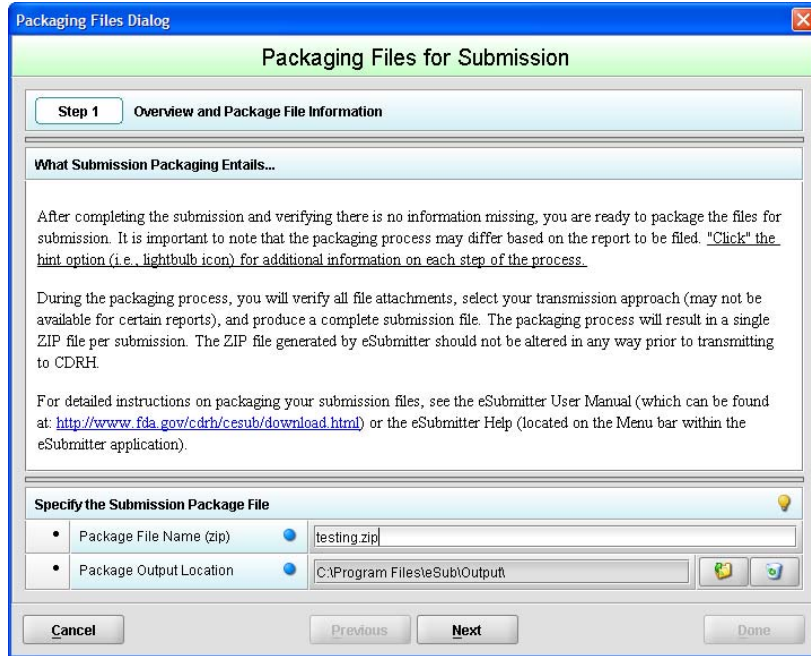
### Warning



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.

## Subsection 4.5: Completing a Submission (Packaging Submission Files)

### Packaging Files Dialog Box



### Step 1: Overview and Package File Information

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

#### Action

#### Graphic

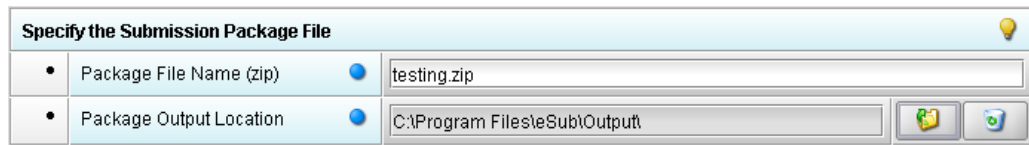
1. Specify the submission package file name.
  - The **Package File Name (.zip)** text box identifies the default zip file name for the submission. (eSubmitter automatically uses the submission name for the zip file.) Make a note of the name for the zip file.
2. Specify the submission output location.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



Select

## Subsection 4.5: Completing a Submission (Packaging Submission Files)

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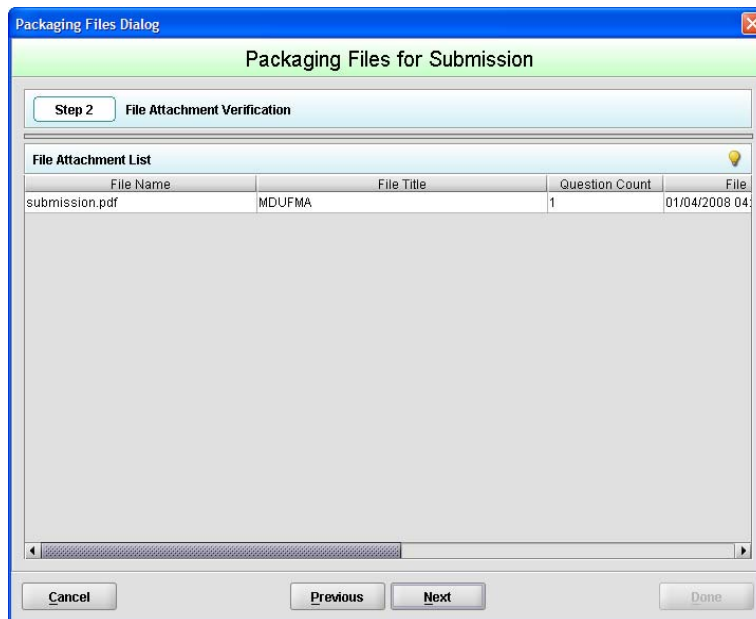


The dialog box titled "Specify the Submission Package File" contains two input fields. The first field, "Package File Name (zip)", has the text "testing.zip" entered. The second field, "Package Output Location", has the text "C:\Program Files\leSub\Output\" entered. To the right of the second field are two icons: a folder icon and a lightbulb icon.

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



### Step 2: File Attachment Verification



The "Packaging Files Dialog" window is titled "Packaging Files for Submission". It shows "Step 2" and "File Attachment Verification". Below this is a "File Attachment List" table with a lightbulb icon in the top right corner.

File Name	File Title	Question Count	File
submission.pdf	MDUFMA	1	01/04/2008 04:




At the bottom of the dialog are four buttons: "Cancel", "Previous", "Next", and "Done".

This section lists all file attachments used in the submission.



## Subsection 4.5: Completing a Submission (Packaging Submission Files)

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Action	Graphic
1. Check the list to ensure that all of the appropriate file attachments are listed (only files referenced in responses will be included). See above for an example.	
2. Check the question counts to confirm that the files are attached.	
<ul style="list-style-type: none"> <li>➤ <b>NOTE:</b> If a file appears to be missing from the list, go to the <b>Submission File List</b> within eSubmitter (File Menu &gt; Tools &gt; Submission File List). In the <b>Master File List</b>, 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.</li> </ul>	
3. Check the file dates, size, and locations to ensure the correct versions of the files are provided.	
4. Click <b>Next</b> to proceed to <b>Step 3</b> and continue packaging the submission.	
<b>OR</b>	
Click <b>Previous</b> to go back to <b>Step 1</b> .	
<b>OR</b>	
Click <b>Cancel</b> and exit the <i>Package File Dialog</i> box.	

## Subsection 4.5: Completing a Submission (Packaging Submission Files)

### Step 3: Transmission Approach, Submittal Letter, and Packaging

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

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

The screenshot shows a dialog box titled "Packaging Files Dialog" with a subtitle "Packaging Files for Submission". The current step is "Step 3: Transmission Approach, Submittal Letter, Package Creation". The dialog is divided into three main sections:

- Select Transmission Approach:** This section contains a list item "Transmission Approach" with two radio button options: "Send submission in the mail on a CD" (which is selected) and "Send submission electronically through the Gateway".
- Output Submittal Letter:** This section contains two list items: "Submittal Letter" and "Attach Signed Submittal Letter". The "Submittal Letter" item has a "View/Print Submittal Letter..." button next to it.
- Produce Submission Package:** This section contains a "Package Submission Files" button and a progress indicator showing "0%".

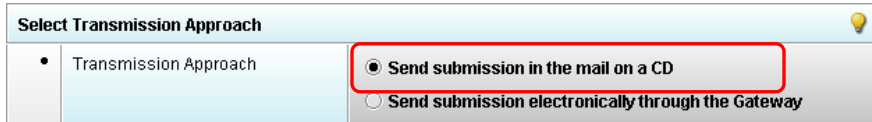
At the bottom of the dialog, there are four buttons: "Previous", "Next", "Cancel", and "Done".

## Subsection 4.5: Completing a Submission (Packaging Submission Files)

Select  
Transition  
Approach (may  
or may not be  
applicable)

Choose the selected approach to send your submission to FDA.

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



The screenshot shows a dialog box titled "Select Transmission Approach". It contains a list item "Transmission Approach" with two radio button options. The first option, "Send submission in the mail on a CD", is selected and highlighted with a red rectangular box. The second option, "Send submission electronically through the Gateway", is unselected.

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

**NOTE:** If you plan to send your submission through the ESG, you will need to register to use the ESG and set up an account. Please see [FDA ESG](#) for more information regarding the ESG.

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



The screenshot shows a dialog box titled "Output Submittal Letter". It contains two list items. The first item, "Submittal Letter", has a button labeled "View/Print Submittal Letter...". The second item, "Attach Signed Submittal Letter", has a blue circular icon and a text input field. A red rectangular box highlights the "View/Print Submittal Letter..." button.

Output Submittal  
Letter (may or  
may not be  
applicable)

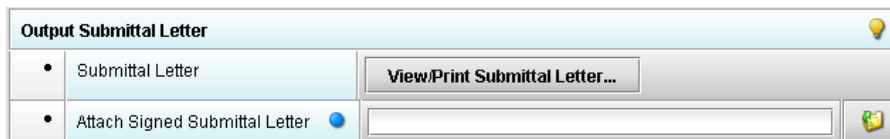
Follow the instructions below for the Output Submittal Letter.

### Action

### Graphic

1. Click the  button, as shown below.

## Subsection 4.5: Completing a Submission (Packaging Submission Files)

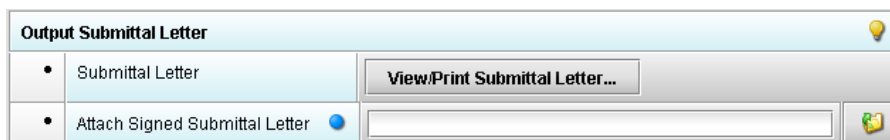


2.
  - a. Ensure that your submittal letter is accurate.
  - b. Print and sign the submittal letter.
  - c. Prepare to mail the submittal letter (for CD transmission approach)

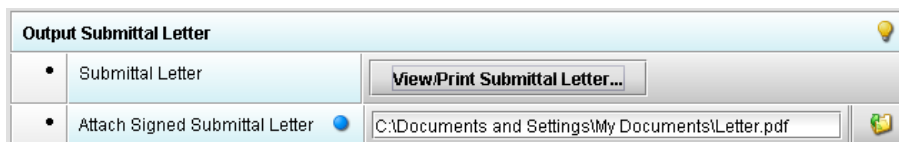
**OR**

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

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



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



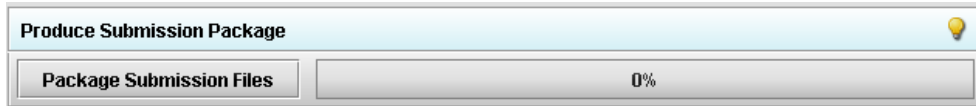
## Subsection 4.5: Completing a Submission (Packaging Submission Files)

**Produce Submission Package (Always available)**

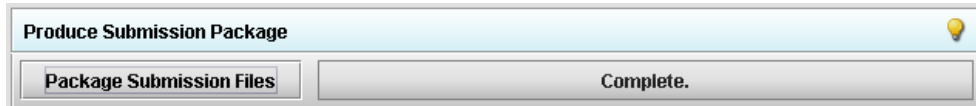
To produce a submission package, follow the instructions below.

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

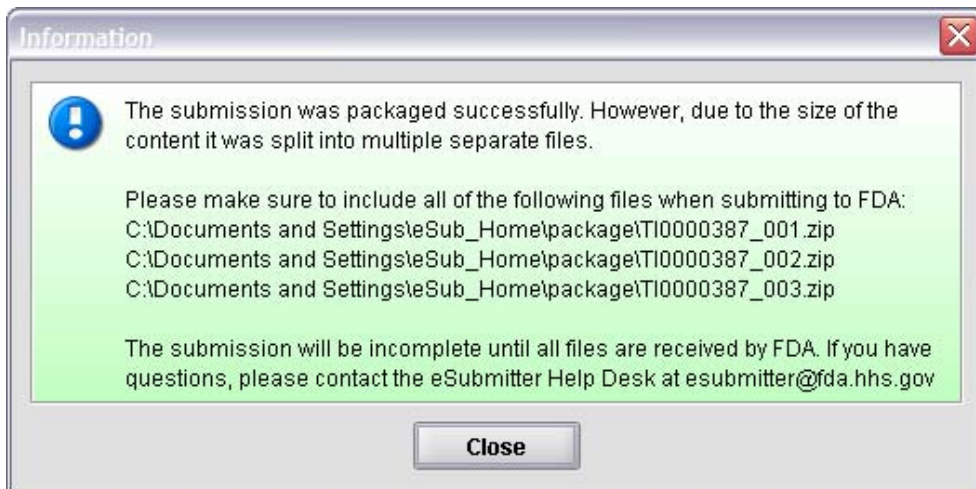


2. **NOTE:** Once the submission has packaged successfully, the status bar will indicate that the packaging is complete (as shown below).



**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

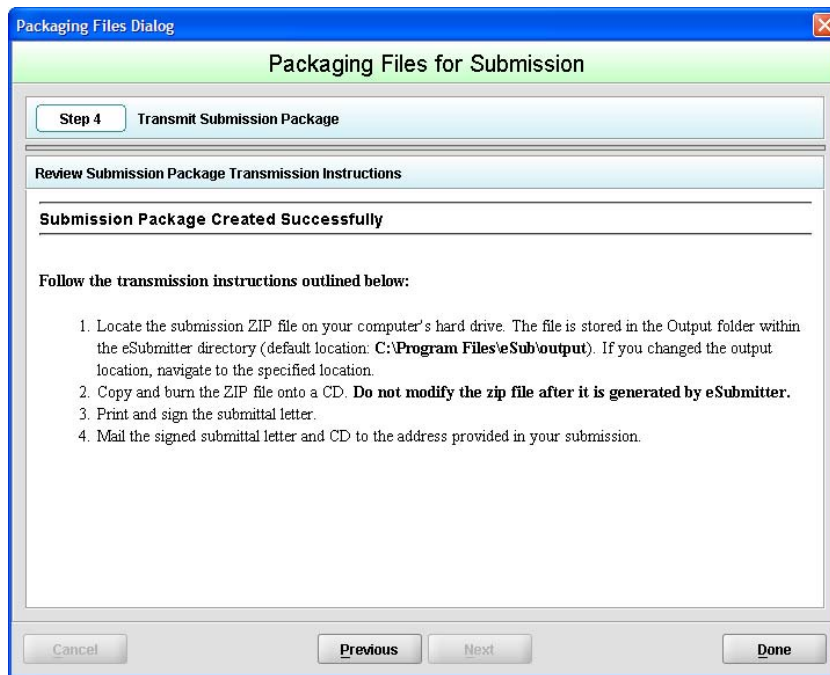
This section provides confirmation that the submission files have been successfully packaged. The submission is ready to be sent to FDA. Follow the instructions below.

#### 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



## Subsection 4.5: Completing a Submission (Packaging Submission Files)

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

A rectangular button with a light gray background and a thin border. The text "Done" is centered in a dark gray font.

**OR**

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

A rectangular button with a light gray background and a thin border. The text "Previous" is centered in a dark gray font.

### 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

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

## Subsection 4.5: Completing a Submission (Packaging Submission Files)

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### Action

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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.**
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- 
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 March 2011, the following is acceptable for each participating program:

**CDER Program:**

ICSR Drug Adverse Event Submissions: Digital signatures are not accepted at this time for ICSR Drug Adverse Event 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.

**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, the CBER program does not accept submissions via the FDA Electronic Submissions Gateway at this time.

**CTP Program:**

Tobacco Establishment Registration, Product Listing and Health Data Submissions: Digital signatures are accepted and required when utilizing the FDA Electronic Submission Gateway to submit registration, listing and additional health data.

**CVM Program:**

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

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.

<b>PDF Area</b>	<b>Recommended PDF Specification</b>
<b>Version</b>	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 <a href="mailto:esubmitter@fda.hhs.gov">esubmitter@fda.hhs.gov</a> to ensure you do not use a feature that is unsupported.
<b>Plug Ins</b>	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.
<b>Page Size and Margins</b>	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.
<b>Page Orientation</b>	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.
<b>Fonts</b>	<p>PDF viewing software automatically substitutes a font to display text if the font used to create the text is unavailable on the reviewer’s computer. Font substitution can affect a document’s appearance and structure, and in some cases it can affect the information conveyed by a document. We cannot guarantee the availability of any one font. Therefore, you should embed all fonts you are using in the PDF files to ensure that those fonts will always be available to the reviewer. When embedding fonts, all characters for the font should be embedded (not just a subset of the fonts being used in the document). One problem associated with embedding fonts is that embedding requires additional computer storage space. Three techniques to help limit the storage space taken by embedding fonts:</p> <ul style="list-style-type: none"> <li>• Limit the number of fonts used in each document</li> <li>• Use only True Type or Adobe Type 1 fonts</li> <li>• Avoid customized fonts.</li> </ul> <p>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.</p>

## Section 5: FDA Recommended PDF File Specifications

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	<p>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.</p> <p>In addition to font colors, keep formatting simple in tables. When extracting a table from the PDF document, the use of light or white font color will not allow the transfer of text back into some word processing documents.</p>
<b>Page Numbering</b>	<p>If a submission includes more than one document, you need not provide pagination for the entire submission. Include page numbers only for individual documents.</p> <p>It is easier to navigate 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.</p>
<b>File Size</b>	<p>An electronic submission can have one or multiple file attachments. There is not a limitation of the total size of the submission, but each file should be limited to 50MB in file size. There are several ways to compress file size, including but not limited to: performing Optical Character Recognition, reducing file size in Adobe and creating logical section breaks.</p> <p>If you have questions about file size, please contact technical support at <a href="mailto:esubmitter@fda.hhs.gov">esubmitter@fda.hhs.gov</a> to ensure the file size is acceptable.</p>
<b>Document Properties: Description Tab</b>	<p>Document properties are used to search for individual documents and to identify the document when found. To modify document properties, from the tool bar navigate to File Document Properties.</p>
<b>Document Properties: Initial View Tab</b>	<p>In the Document Properties box, the Initial View tab can also be found. In the Document Options section, all PDF files should set the Show field as Bookmarks Panel and Page. If there are no bookmarks, set the initial view as Page only. Set the Page Layout and Magnification fields to default.</p>
<b>Document Properties: Security</b>	<p>PDF files are stored as original documents and will not be altered from their original form. Remove any security settings, read-only, or password protection used on the files. Files submitted with security settings will not be accepted.</p>

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

## Section 5: FDA Recommended PDF File Specifications

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<b>Optical Character Recognition</b>	<p>PDF documents produced by scanning paper documents are usually inferior to those produced from an electronic source document such as MS Word. Scanned documents are more difficult to read and do not allow the reviewers to search or copy and paste text for editing. The use of scanned documents should be avoided if at all possible. If scanning cannot be avoided, the following is highly recommended:</p> <ul style="list-style-type: none"><li>• Perform optical character recognition (OCR) on all scanned documents so that the text is searchable</li><li>• Check to see that the content has been correctly converted.</li></ul> <p>If the source document is only available on paper, it should be scanned at resolutions that will ensure the pages are legible both on the computer screen and when printed. At the same time, remember to limit the file size to be less than 50MB. We recommend scanning at a resolution of 300 dots per inch (dpi) to balance legibility and file size. We discourage the use of grayscale or color because of file size. After scanning, avoid re-sampling to a lower resolution.</p> <p><b>For files with images and photographs:</b></p> <p>Also, when creating PDF files containing images, you should not resample images. Re-sampling does not preserve all of the pixels in the original. For photographs, the image should be obtained with a resolution of 600 dpi. If black and white photos are submitted, consider 8-bit gray scale images. If color photos are submitted, consider 24-bit RGB Color Model images. A captured image should not be subjected to non-uniform scaling (i.e., sizing).</p> <p>Files with scanned images and photographs tend to be large in file size. Please do not exceed 50MB for a single file. Consider multiple files for these types of documents.</p> <p><b>Note:</b> Scanned tables and graphs cannot be extracted easily if scanned. Most OCR programs will distort the data in tables and graphs. Convert MS Word documents to PDF, as this method usually retains the formatting.</p> <p><b>For a paper document with handwritten notes:</b></p> <p>Paper documents containing handwritten notes should be scanned at 300 dpi. These handwritten notes should be made in black ink for</p>
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	<p>clarity.</p> <p>If you have questions about creating electronic copies, please contact technical support at <a href="mailto:esubmitter@fda.hhs.gov">esubmitter@fda.hhs.gov</a> to ensure that the format is acceptable prior to developing your submission.</p>
<p><b>Naming PDF Files</b></p>	<p>We are recommending names for folders and selected files in individual guidances for specific submission types. For uniformity, we hope that you use our specific naming conventions when they are provided. Reviewers are trained to look for these folders and files, and using the recommended names should help avoid misunderstandings, improve communication, and speed the review of a submission.</p> <p>File names should not contain more than 250 characters. <b>Do not use punctuation, spaces, or other nonalphanumeric symbols in file names when naming the files for attachments.</b> For example, do not use slashes (/) (\), tildes (~), asterisks (*), periods (.), brackets [ ], single quotation marks (‘), double quotation marks (“) or parentheses ( ). Once the file is attached to a question, it can be selected as an attachment to other questions, if appropriate.</p> <p>The eSubmitter tool supports the following file types:</p> <ul style="list-style-type: none"> <li>• Portable Document Format Files (.pdf)</li> <li>• Excel Files (.xls, .csv)</li> <li>• SAS System XPORT Files (.xpt)</li> <li>• Media Files (.wmv, .avi)</li> <li>• Image Files (.gif, .tif, .jpg)</li> <li>• Extensible Markup Language Files (.xml, .dtd)</li> <li>• Archive/Compressed Files (.zip)</li> <li>• Standard Generalized Markup Language Files (.sgml)</li> <li>• MDL Molfiles Files (.mol)</li> </ul> <p>However, based on the application or report you are submitting, the question(s) may have restrictions on which file types you are allowed to attach. For example, some questions may allow you to attach any of the file types supported by eSubmitter and some may only allow you to attach PDF and Excel files as the question response or supporting documentation.</p>

## Section 6: User Support

### Introduction

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

For CVM related technical support or general inquiries, please contact: [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

For CBER related technical support or general inquiries, please contact: [CBER\\_eSubmitter\\_program@fda.hhs.gov](mailto:CBER_eSubmitter_program@fda.hhs.gov)



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# Appendix

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## CVM Recommended 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, that don't include data needed for further processing in Portable Document Format (PDF). PDF is an open, published format created by Adobe Systems Incorporated and accepted as an ISO standard under ISO 32000. (<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 Veterinary International Conference on Harmonization (VICH).

For data files, CVM recommends that either eXtensible markup language (XML) file format or SAS XPORT (XPT) be used. The file specifications contained within this manual are recommendations from CVM and over time may evolve to accommodate a changing technology.

## ***Portable Document Format (PDF) Specifications***

<b>PDF Area</b>	<b>Recommended PDF Specification</b>
<b>Version</b>	<p>The PDF files should be created to support the PDF/A standard. Everything needed to render or print a PDF/A file must be contained within the file. This includes all visible content like text, raster images, vector graphics, fonts, color information, and much more. It also means that a wide range of external content references are disallowed, including audio and video content, JavaScript, and executable files. All embedded fonts must be legally embeddable for unlimited, universal rendering.</p> <p>The PDF files also 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. CVM currently is running Adobe Acrobat 8.0 so if you are planning on submitting Adobe Acrobat 9.0 files, please contact technical support at <a href="mailto:cvmsubmitter@fda.hhs.gov">cvmsubmitter@fda.hhs.gov</a> to ensure you do not use a feature that is unsupported.</p>
<b>Plug Ins</b>	<p>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.</p>
<b>Page Size and Margins</b>	<p>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. However, for files that contain images of labeling page size should be commensurate with the size of the label being presented. You should present the label image in the size as if the labeling was in front of you.</p>
<b>Page Orientation</b>	<p>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.</p>
<b>Fonts</b>	<p>PDF viewing software automatically substitutes a font to display text if the font used to create the text is unavailable on the reviewer's computer. Font substitution can affect a document's appearance and structure, and in some cases it can affect the information conveyed by a document. We cannot guarantee the availability of any one font. Therefore, you should embed all fonts you are using in the PDF files to ensure that those fonts will always be available to the reviewer. When embedding fonts, all characters for the font should be embedded (not just a subset of the fonts being used in</p>

	<p>the document). One problem associated with embedding fonts is that embedding requires additional computer storage space. Three techniques to help limit the storage space taken by embedding fonts:</p> <ul style="list-style-type: none"> <li>• limit the number of fonts used in each document</li> <li>• use only True Type or Adobe Type 1 fonts</li> <li>• avoid customized fonts</li> </ul> <p>Resizing a document because the contents are too small to read is inefficient.</p> <p>We believe that Arial, 11-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 11-points should be avoided whenever possible. We recommend the use of a black font color.</p> <p>Blue font may be used on hypertext links. If a font color other than black is used, avoid light colors that do not view well on computer screens or do not print well on grayscale printers if printing is necessary. It is advised that you test the color reproduction prior to submission by printing sample pages from the document using a grayscale printer.</p> <p>In addition to font colors, keep formatting simple in tables. When extracting a table from the PDF document, the use of light or white font color will not allow the transfer of text back into some word processing documents.</p>
<b>Page Numbering</b>	<p>If a submission includes more than one file, you need not provide pagination for the entire submission. Pagination should occur on an individual attached file basis.</p>
<b>File Size</b>	<p>An electronic submission can have one or multiple file attachments. There is not a limitation of the total size of the submission, but each file should be limited to 100MB in file size. There are several ways to compress file size, including but not limited to: performing Optical Character Recognition, reducing file size in Adobe and creating logical section breaks.</p> <p>If you have questions about file size, please contact technical support at <a href="mailto:cvmesubmitter@fda.hhs.gov">cvmesubmitter@fda.hhs.gov</a> to ensure the file size is acceptable.</p>
<b>Document Properties: Description Tab</b>	<p>Document properties are used to search for individual documents and to identify the document when found. To modify document properties, from the tool bar navigate to File Document Properties.</p>
<b>Document Properties: Initial View Tab</b>	<p>In the Document Properties box, the Initial View tab can also be found. In the Document Options section, all PDF files should set the Show field as Bookmarks Panel and Page. If there are no bookmarks, set the initial view as Page only. Set the Page Layout and Magnification fields to default.</p>

<b>Document Properties: Security</b>	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.
<b>Indexing PDF Documents</b>	<p>Full text indexes are used to help find specific documents and/or to search for text within documents. When a document or group of documents is indexed, all words and numbers in the file and all information stored in the Document Information fields are stored in special index files that are functionally accessible using the search tools available in Acrobat.</p> <p>Portions of a document that are imaged are not indexed. Even if the document only contains images, the text in the Document Information fields of the file will be indexed. All PDF files should be full-text searchable prior to submitting to the FDA.</p>
<b>Bookmarks and Hypertext Links</b>	<p>Bookmarks and hyperlinks should be used to assist the reviewers in navigating through the content of the submission. If you used either bookmarks or hypertext links, consider the following:</p> <p>Use meaningful bookmarks (e.g., the title of the section, name of a study, data set, or facility). This will aid the reviewer in locating information and navigating the submission.</p> <p>Bookmark references can be created for the heading of a section, subsection or title of figures and tables within the document. In general, including a bookmark to the main table of contents for a submission or item is helpful. Make the bookmark hierarchy identical to the table of contents.</p> <p>Use hyperlinks within the file. Hyperlinks are used to improve navigation through PDF documents and are encouraged. Hyperlinks can be designated by rectangles using thin lines or by blue text or you can use invisible rectangles for hypertext links in a table of contents to avoid obscuring text. Hyperlinks throughout the body of the document to supporting annotations, related sections, references, appendices, tables, or figures that are not located on the same page are helpful and improve navigation efficiency. When creating bookmarks and hyperlinks, the magnification setting should be set to Inherit Zoom so that the destination page displays at the same magnification level that the reviewer is using for the rest of the document.</p> <p><b>Important Note:</b> Hyperlinks <u>between</u> individual PDF document files are not currently supported and any absolute links that reference across files will not work.</p> <p>In general, for documents with a table of contents, provide bookmarks and hypertext links for each item listed in the table of</p>

	<p>contents including all tables, figures, publications, other references, and appendices. These bookmarks and hypertext links are essential for the efficient navigation through documents.</p>
<p><b>Optical Character Recognition</b></p>	<p>PDF documents produced by scanning paper documents are usually inferior to those produced from an electronic source document such as MS Word. Scanned documents are more difficult to read and do not allow the reviewers to search or copy and paste text for editing. The use of scanned documents should be avoided if at all possible. If scanning cannot be avoided, the following is highly recommended:</p> <ul style="list-style-type: none"> <li>• Perform optical character recognition (OCR) on all scanned documents so that the text is searchable</li> <li>• Check to see that the content has been correctly converted.</li> </ul> <p>If the source document is only available on paper, it should be scanned at resolutions that will ensure the pages are legible both on the computer screen and when printed, if necessary. At the same time, remember to limit the file size to be less than 100MB. We recommend scanning at a resolution of 300 dots per inch (dpi) to balance legibility and file size. After scanning, avoid re-sampling to a lower resolution.</p> <p><b>For files with images and photographs:</b>  Also, when creating PDF files containing images, you should not resample images. Re-sampling does not preserve all of the pixels in the original. For photographs, the image should be obtained with a resolution of 600 dpi. If black and white photos are submitted, consider 8-bit gray scale images. If color photos are submitted, consider 24-bit RGB Color Model images. A captured image should not be subjected to non-uniform scaling (i.e., sizing). Files with scanned images and photographs tend to be large in file size. Please do not exceed 100MB for a single file. Consider multiple files for these types of documents.</p> <p><b>Note:</b> Scanned tables and graphs cannot be extracted easily if scanned. Most OCR programs will distort the data in tables and graphs. Convert MS Word documents to PDF, as this method usually retains the formatting.</p> <p><b>For a paper document with handwritten notes:</b>  Paper documents containing handwritten notes should be scanned at 300 dpi. These handwritten notes should be made in black ink for clarity.</p> <p>If you have questions about creating electronic copies, please contact technical support at <a href="mailto:cvmesubmitter@fda.hhs.gov">cvmesubmitter@fda.hhs.gov</a>.</p>

<p><b>Naming PDF Files</b></p>	<p>We suggest uniformity be used when naming files. When naming files, do not use punctuation, spaces, or other non-alphanumeric symbols in file names when naming the files for attachments. For example, do not use slashes (/) (\), tildes (~), asterisks (*), periods (.), brackets [ ], single quotation marks ('), double quotation marks (") or parentheses ( ). Once the file is attached to a question, it can be selected as an attachment to other questions, if appropriate.</p> <p>The eSubmitter tool supports the following file types:</p> <ul style="list-style-type: none"> <li>• Portable Document Format Files (.pdf)</li> <li>• Excel Files (.xls, .csv)</li> <li>• SAS System XPORT Files (.xpt)</li> <li>• Media Files (.wmv, .avi)</li> <li>• Image Files (.gif, .tif, .jpg)</li> <li>• Extensible Markup Language Files (.xml, .dtd)</li> <li>• Archive/Compressed Files (.zip)</li> <li>• Standard Generalized Markup Language Files (.sgml)</li> <li>• MDL Molfiles Files (.mol)</li> </ul> <p>However, CVM submission will only permit <b>PDF</b>, <b>XML</b>, and/or <b>XPT</b> files. Based on the question you are answering, the question may have restrictions on which file types you are allowed to attach. For example, some questions may allow you to attach any of the three file types permitted by CVM and some may only allow you to attach PDF and XML files as the questions response or supporting documentation.</p>
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### ***Facsimile and Final Printed Labeling (FPL) in PDF files***

Final printed labeling (FPL) are required to be submitted as part of the animal drug approval submission. However, in lieu of FPL CVM permits the submission of facsimile labeling with the (A)NADA as long as the FPL is submitted prior to marketing the approved product. In the electronic world, facsimile labeling would represent the 2-dimensional aspect of the labeling components, including color, size, and fonts, without the labeling actually being produced. The PDF files with facsimile labeling need to contain the images/graphics of the labeling components without actual pictures of the final printed label components printed on their intended media (bag, foil pouch, syringe, etc.). The PDF files for FPL should contain the actual pictures of the different label component embedded at their actual size and color. To aid in the review of both facsimile and FPL submissions, CVM recommends that both a pantone ruler (for color verification) and a photographic ruler (for size verification) be included in all photographs of final printer labeling.

### ***Extensible Markup Language (XML) Specifications***

The use of XML file format within the CVM eSubmitter templates have been limited to either the submission of Stability data or other data questions. One should verify that when an XML file is created, it is not created with proprietary formatting as can occur with many common word processing programs. The created XML file, at a minimum, should be viewable with any of the common web browser. When creating XML files to support the answers to stability questions,

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the file should conform to the HL7 standard. For more information visit the [CVM eSubmitter webpage](#),

### ***SAS Transport (XPT) Specifications***

SAS Transport files are use to package both SAS programs as well as SAS data. Currently, CVM does not have specific recommendations on how these files should be constructed. Therefore, stakeholders are encouraged to contact CVM's Biostatistics Teams (HFV-163 and 164).