

FDA eSubmitter

User Manual



Document Version 4.5

March 16, 2009

DOCUMENT HISTORY

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Version 1.1	August 27, 2004	Updated to reflect the enhancements incorporated in the Official OIVD Pilot Release (Software v1.00.01)
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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.

FDA eSubmitter

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Section 1: Introduction

Contents

This section contains the following topics:

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

Subsection 1.1: System Background

Introduction

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

If using the eSubmitter software is not desirable, you may continue to complete hard copies of the report.

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.
- **Section 7** provides a list of frequently asked questions and the corresponding answers.

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 HTML, 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.**

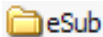

Note: If you do not have a previous version of eSubmitter, proceed to installing the current version of eSubmitter software.

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

Action	Graphic
<p>1. Use Windows Explorer to navigate to the label for the computer's installed hard drive, e.g., Local Disk (C:). For example, on a computer with Windows 2000:</p> <ul style="list-style-type: none">• 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:).	 Program Files
<p>2. Double-click on the label for the hard drive to display its contents.</p>	
<p>3. Navigate to and double-click to open the Program Files file folder.</p>	

Continued on Next Page

Subsection 1.3: Software Installation

4. Navigate to and click to open the **eSub** file folder. You will see the folder's contents in the pane on the right-hand side of the screen. 
5. Double-click on the **Uninstall.exe** file, and follow the instructions provided. 

Note: If you do not see the **Uninstall.exe** file:

- a. Locate and double-click to open the **JExpress** file folder.
 - b. Double-click on the **uninstall.bat** file, and follow the instructions provided.
-
6. When the previous version has been uninstalled, you are ready to install the current version of the eSubmitter software. See the following procedure.
-

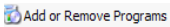
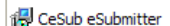
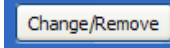
Uninstall Instructions

Some users may be unable to uninstall eSubmitter by following the instructions above due to the permissions and rights restrictions established on their system during the time of the install.

To ensure the uninstall process was successful, follow the instructions below.

Action	Graphic
<ol style="list-style-type: none">1. Use Windows Explorer to navigate to the Control Panel. For example, on a computer with Windows 2000:<ul style="list-style-type: none">• Open Windows Explorer.• Double-click My Computer to display its contents.• Look for the label of the Control Panel.	
<ol style="list-style-type: none">2. Double-click on the label for the Control Panel to display its contents.	

Subsection 1.3: Software Installation

3. Navigate to and double-click to open the **Add or Remove Programs** location. 
4. Locate and click on the **eSubmitter** program icon. 
5. Click **Change/Remove**. 
6. Click **Yes** when the question window appears – “Are you sure you want to uninstall eSubmitter?”
7. Ensure the program is entirely removed by navigating to the program file and deleting it. 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:)**.
8. Locate the **eSub** program file.
9. Right click, and select **Delete**.

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 <https://www.fda.gov/cdrh/cesub/>. To install the latest version of the eSubmitter software from this web page, follow the instructions below.

Continued on Next Page

Subsection 1.3: Software Installation

Action	Graphic
1. Click the link for downloading the eSubmitter Software.	
Download eSubmitter Software	
2. Follow the instructions provided. Following the instructions, the software will be installed locally on your hard drive in C:\Program Files\eSub .	
Notes: 1. You can change the location where the software is installed by changing the file path on the Installation Directory dialog box when it appears.	
2. The software may be installed on a network. eSubmitter has a file locking option that you set to prevent users from accidentally overwriting the work of another. For details, see <i>Networking</i> on page 21.	

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 <http://www.fda.gov/cdrh/cesub/vista.html> on the FDA eSubmitter website for the latest information on successfully installing the tool within Windows Vista.

Installation Instructions from a CD-ROM

To install the latest version of the eSubmitter software from a CD-ROM:

Subsection 1.3: Software Installation

Action	Graphic
1. Windows Explorer should be open on your computer's desktop.	
2. Insert the eSubmitter CD-ROM in the CD drive of your computer.	
3. Navigate to the directory of the CD drive, if you do not see it on your screen. For example, on a computer with Windows 2000: <ul style="list-style-type: none"><li data-bbox="646 764 1019 791">• Open Windows Explorer.<li data-bbox="646 814 1179 879">• Double-click My Computer to display its contents.<li data-bbox="646 903 1198 968">• Look for the label for the CD drive. For example, (E:).	
4. Double-click on the label for the CD drive to display its contents.	
5. Double-click on the jinstall.exe file.	
6. Follow the instructions provided. Following the instructions, the software will be installed locally on your hard drive in C:\Program Files\eSub .	
7. Note: You can change the location where the software is installed by changing the file path on the Installation Directory dialog box when it appears.	
8. When the installation is complete, remove the CD-ROM from the CD drive.	
9. Note: 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 21.	

Subsection 1.3: Software Installation

Proxy Server Instructions

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

The properties file is located in the application's JExpress subdirectory (**Program Files\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:

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Re-open an Existing Submission	34

Subsection 2.1: Starting the Software

Introduction

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

Starting the Software

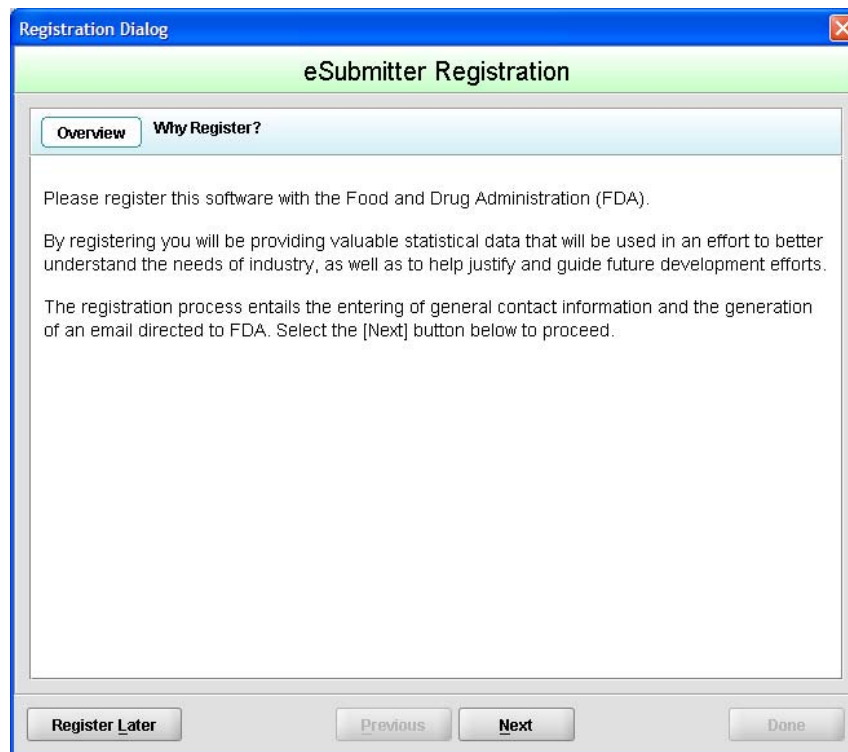
To start up the eSubmitter application, follow the instructions below.

Action

Graphic

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

Registration Dialog Box



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

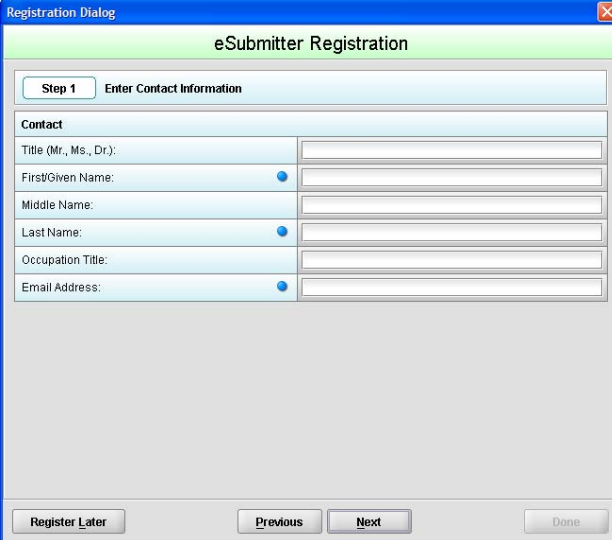


/



Subsection 2.1: Starting the Software

Registration Dialog Box: Contact Information



The screenshot shows a 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 several input fields, each with a blue dot indicating it is required: "Title (Mr., Ms., Dr.)", "First/Given Name", "Middle Name", "Last Name", "Occupation Title", and "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.

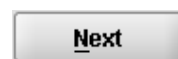


Registration Dialog Box: Address Information



The screenshot shows the same "Registration Dialog" window, but the tab is now "Step 2 Enter Address Information". The form includes fields for "Establishment Name", "Country" (with radio buttons for "United States of America" and "Other (select below)"), "Address - Line 1", "Address - Line 2", "City", "State, Province, or Territory" (a dropdown menu), "Post Office or Zip Code", and "Phone Numbers" (with a field for "Telephone number" and a format "() - - Ext. "). The "Next" button is highlighted. At the bottom are buttons for "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.



Subsection 2.1: Starting the Software

Registration Dialog Box: Generate Email

Registration Dialog

eSubmitter Registration

Step 3 Generate Email

You provided the following information:

John Smith
john.smith@sample.com
Sample
Sample
Rockville, MD, 20850, US
(301) 111-2222

Please verify the information and select the link below to generate an email to send to FDA.
[Generate Email](#)

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

Register Later Previous Next Done

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.

Next

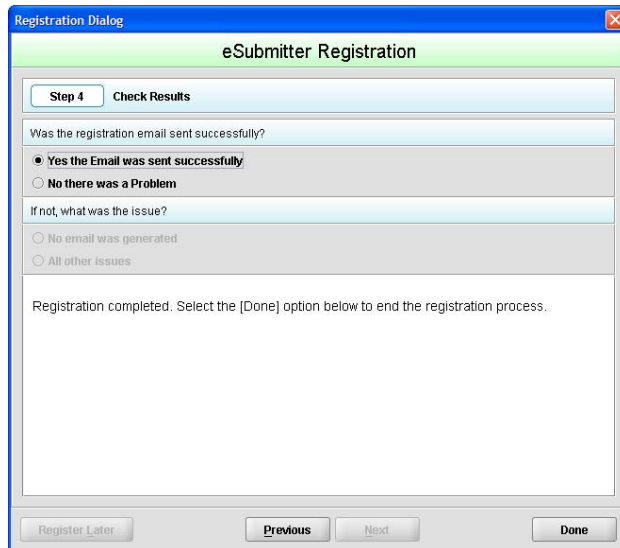
/

Previous

Continued on Next Page

Subsection 2.1: Starting the Software

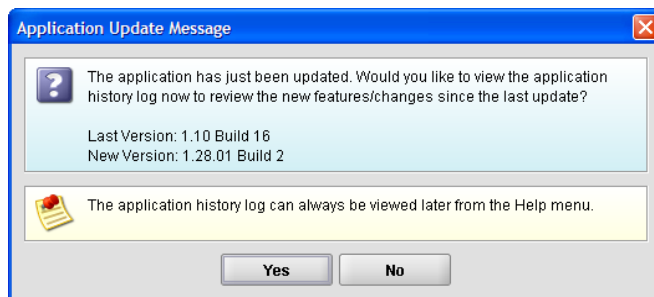
Registration Dialog Box: Check Results



9. Select the button corresponding to either **Yes the Email was sent correctly** or **No there was a problem**.
10. Click **Done** if the email was successful and to complete the registration process.
11. If the eSubmitter software has been updated and you are connected to the Internet, you will see an *Application Update Message* to notify you that the software has changed (as shown below).



Application Update Message



Continued on Next Page

Subsection 2.1: Starting the Software

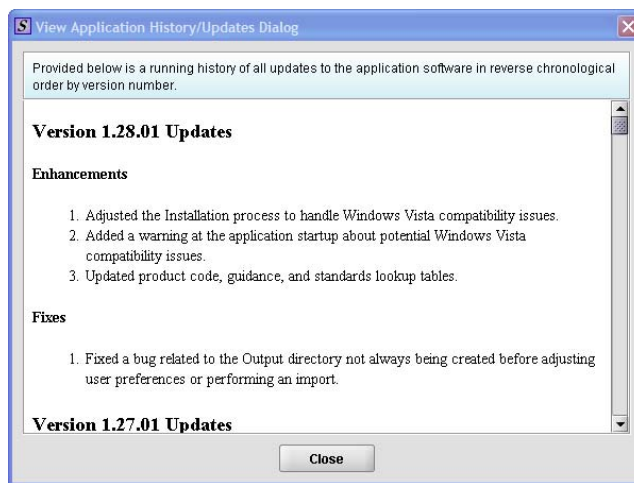
12. On the **Application Update Message**:

- Click **No** if you do not wish to see a list of the changes to the software. You can review the changes at a later time if you wish.
- Click **Yes** if you do want to review a list of changes to the software. You see the *View Application History/Updates Dialog* box (as shown below).

No

Yes

View Application History/Updates Dialog Box



13. Click **Close** when you are finished reviewing the list of changes. The dialog box closes.

Close

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




Continued on Next Page

Subsection 2.1: Starting the Software

Intro Screen






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



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

Continued on Next Page

Subsection 2.1: Starting the Software

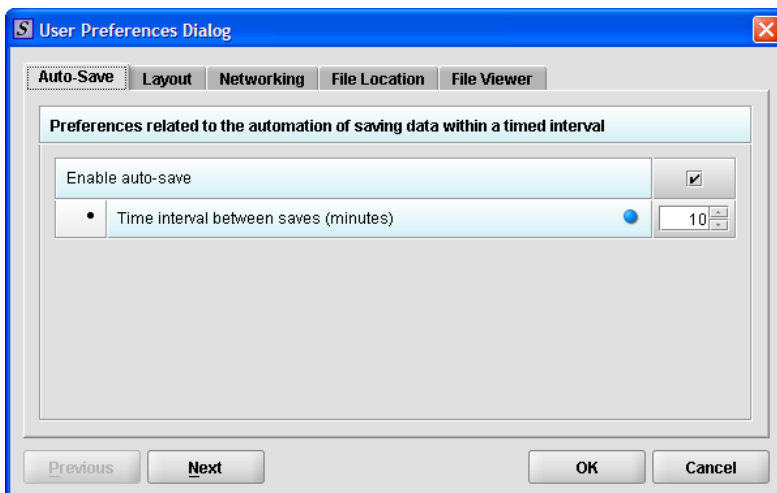
Exit Application		Closes the eSubmitter application.
Help Topics		Displays the <i>Help Menu</i> , which provides instructional information and support for utilizing the eSubmitter application.
Forward Navigation Arrow		This arrow allows you to move forward through the Message Tabs .
Backward Navigation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

Subsection 2.2: Setting User Preferences

Introduction eSubmitter allows you to set preferences for the following categories:

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

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.

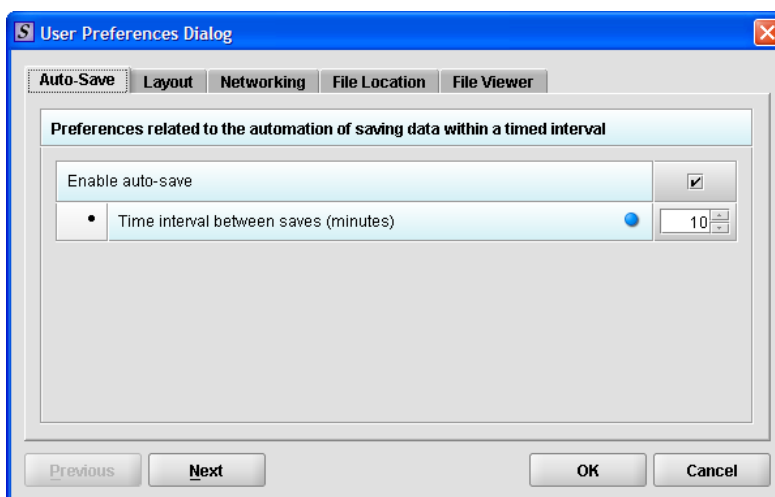
Continued on Next Page

Subsection 2.2: Setting User Preferences


Auto Save

- **Auto Save** – When this option is enabled, eSubmitter automatically saves your report while you work. You can also set the interval for how often you want to save your report. At default, auto-save is automatically enabled and set to save files at 10-minute intervals.

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



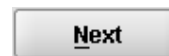
To change the auto-save option:

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

Continued on Next Page

Subsection 2.2: Setting User Preferences

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



OR

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



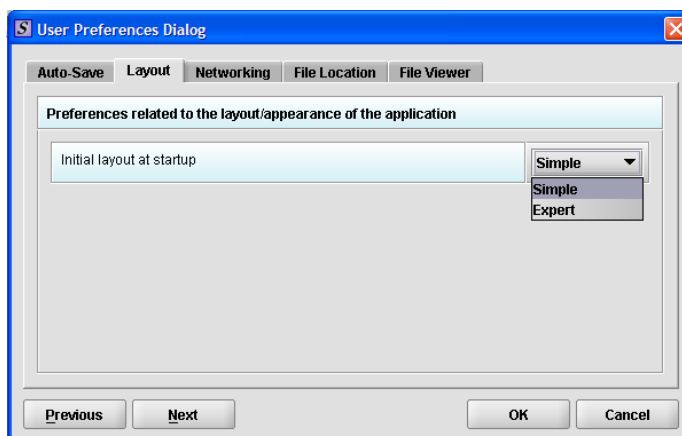
OR

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



Layout

Allows you to set whether you want eSubmitter to open reports in the simple or expert layout when you start up the application. At default, eSubmitter opens reports in the simple layout. For more information, see descriptions in the *Application Window* section on page 36.



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

Action

Graphic

-
1. In the initial layout box, select **Simple** or **Expert** from the drop-down menu.
-

Continued on Next Page

Subsection 2.2: Setting User Preferences

-
2. If you want to change the settings for networking, click **Next** or the **Networking** tab. See the description for **Networking** below.



OR

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



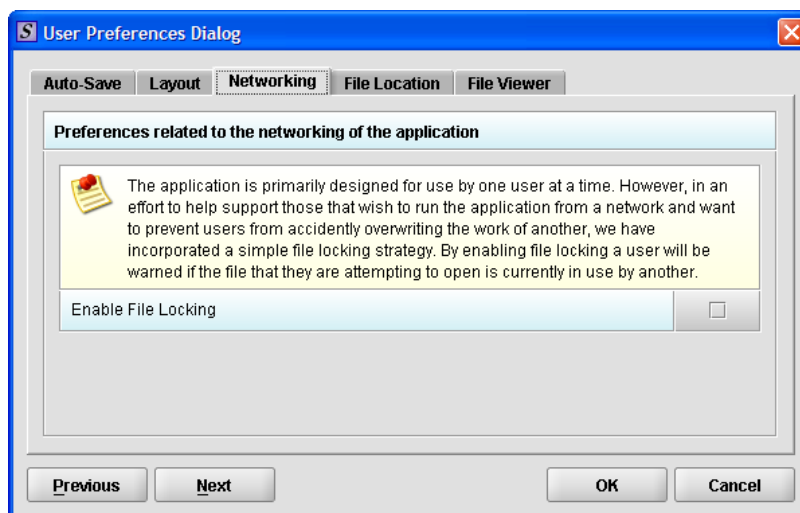
OR

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



Networking





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



To enable file locking, follow the instructions below.

Continued on Next Page

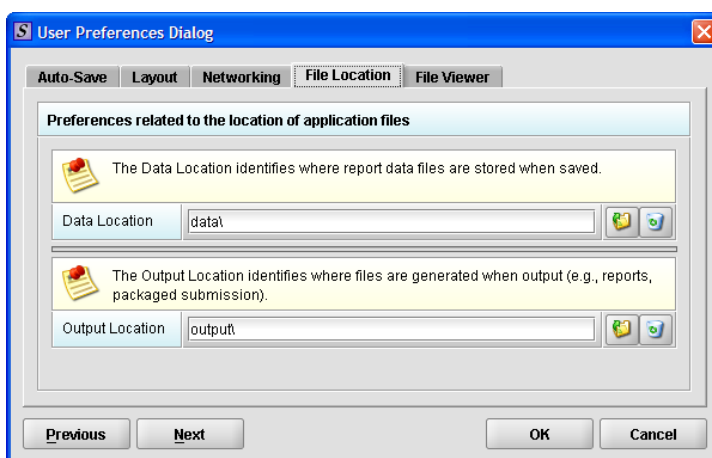
Subsection 2.2: Setting User Preferences

Action	Graphic
1. Click to select the Enable File Locking checkbox (to turn file locking on) or clear the checkbox (to turn file locking off).	
2. If you want to change the settings for networking, click Next or the File Location tab. See the description for File Location below.	
OR	
If you are finished and satisfied with your changes, click OK to close the <i>User Preferences Dialog</i> box with your changes saved.	
OR	
Click Cancel to close the <i>User Preferences Dialog</i> box without saving any changes.	

Subsection 2.2: Setting User Preferences

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 87.



To change the file location for the data folder and/or the output folder:

Action

Graphic

1. Click the **Select Location** icon to the right of the text box.

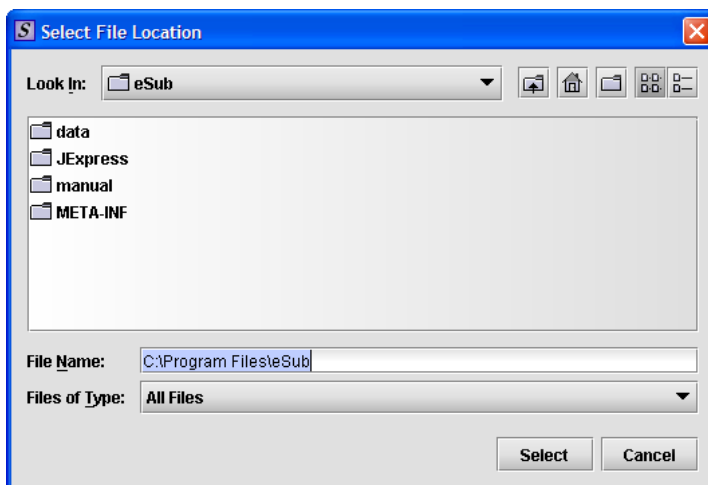


Continued on Next Page

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.

Subsection 2.2: Setting User Preferences

Select File Location Box



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



Recommended Location:

If installed on a Network drive (on 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 Settings\eSub_Home**.

Subsection 2.2: Setting User Preferences

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



OR

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



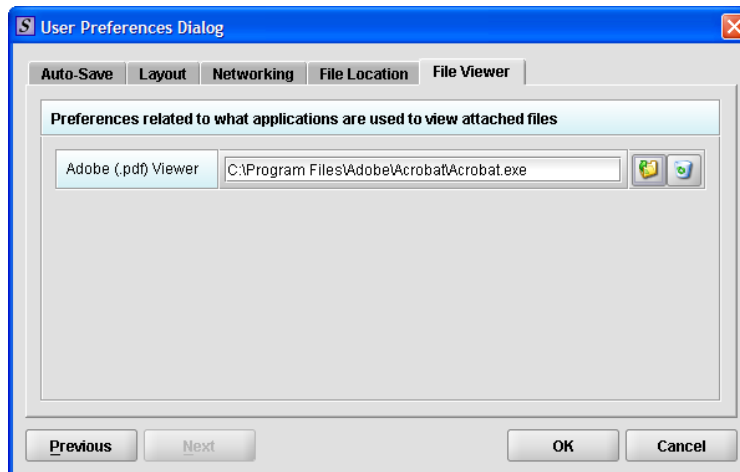
OR

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



File Viewer

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



Follow these instructions to set up your PDF viewer:

Action

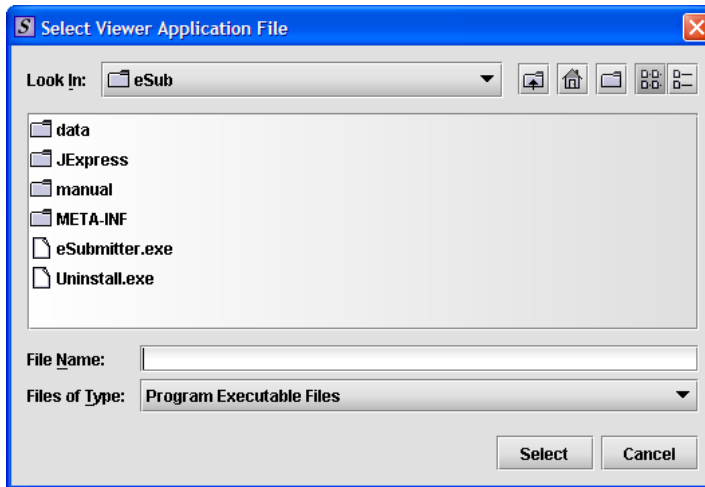
Graphic

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



Subsection 2.2: Setting User Preferences

Select Viewer Application File Box



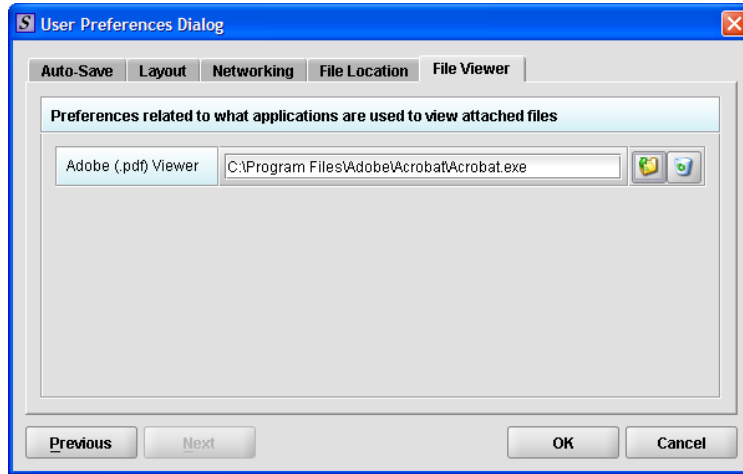
Continued on Next Page

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

Select

Subsection 2.2: Setting User Preferences

User Preferences Dialog Box



4. Click **OK**.



Subsection 2.3: Creating a New Submission

Introduction

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

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

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

Create a New Submission

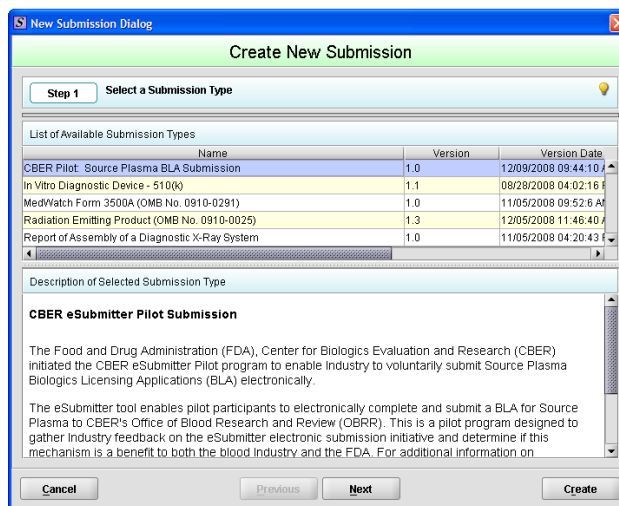
Follow the steps below to create a new blank submission from scratch:

Action

Graphic

1. The eSubmitter application should be open on your computer desktop. If it is open, and you see the *Intro Screen*, go to step 2. (If it is not open, open the application first by following the instructions in *Starting the Software* on page 11.)

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).



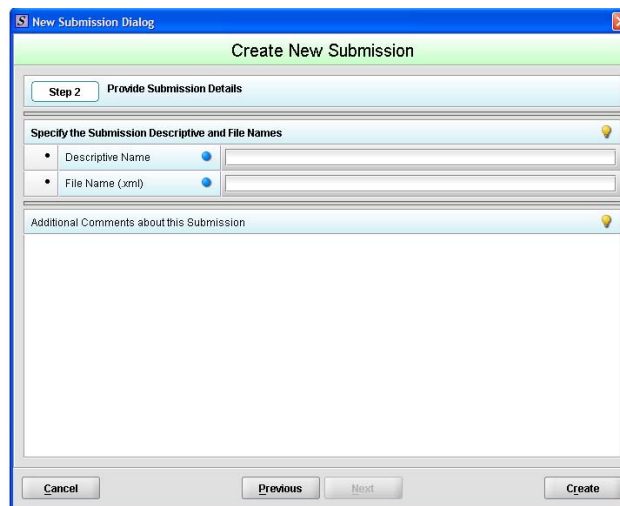
Subsection 2.3: Creating a New Submission

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**.



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

A screenshot of a software dialog box titled "New Submission Dialog" with a subtitle "Create New Submission". The dialog is divided into two steps. The current step is "Step 2: Provide Submission Details". Under the heading "Specify the Submission Descriptive and File Names", there are two input fields: "Descriptive Name" and "File Name (.xml)". Both fields have a blue dot to their left, indicating they are required. Below these fields is a large text area labeled "Additional Comments about this Submission". At the bottom of the dialog, there are four buttons: "Cancel", "Previous", "Next", and "Create".

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.)

Continued on Next Page

Subsection 2.3: Creating a New Submission

- **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 250 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).

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

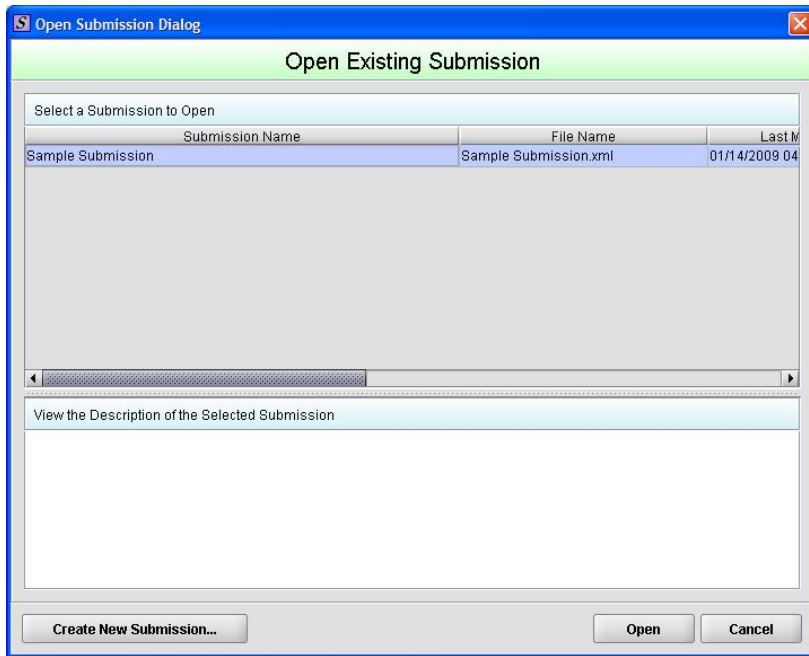
Action

Graphic

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



Open Report Data Dialog Box



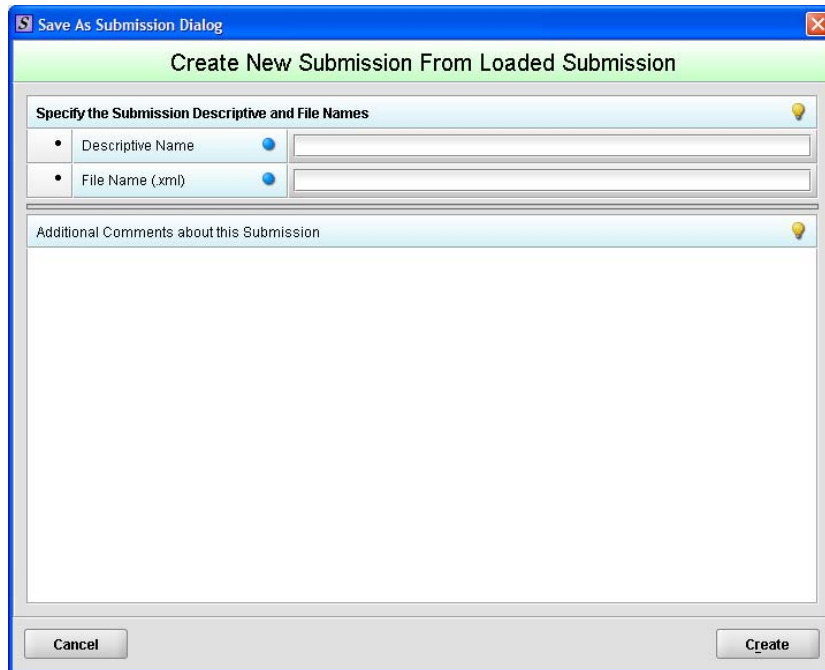
2. Click to select the existing submission report to be used as a template, and click **Open**. The submission report is displayed on your computer.
3. Click **File > Save As**. The *Save Submission As Dialog* box is displayed (as shown below).



Continued on Next Page

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

Save Submission As Dialog Box



The screenshot shows a dialog box titled "Save As Submission Dialog" with a subtitle "Create New Submission From Loaded Submission". The dialog is divided into three main sections. The top section, "Specify the Submission Descriptive and File Names", contains two required input fields: "Descriptive Name" and "File Name (.xml)", each marked with a blue dot. The middle section is a large text area labeled "Additional Comments about this Submission". The bottom section contains two buttons: "Cancel" on the left and "Create" on the right.

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).
-

Continued on Next Page

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

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



The first screen of your new submission report is displayed.

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

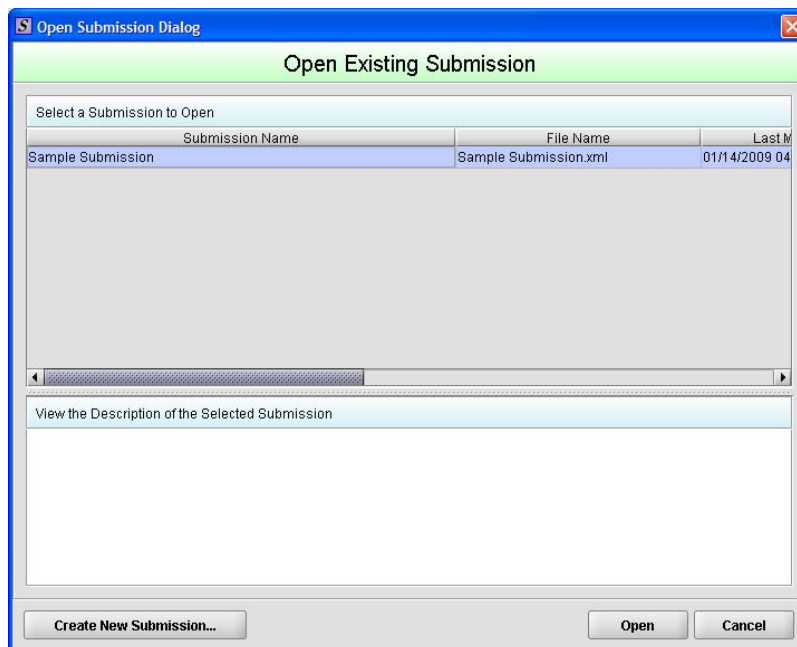
1. Click **File > Open** on the menu bar.

OR

Click  on the tool bar.

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

Open Submission Dialog Box



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



Section 3: Interface

Contents

This section contains the following topics:

Topic	See Page
Application Window	36
Toolbar	41
Menu Bar – Tools	43

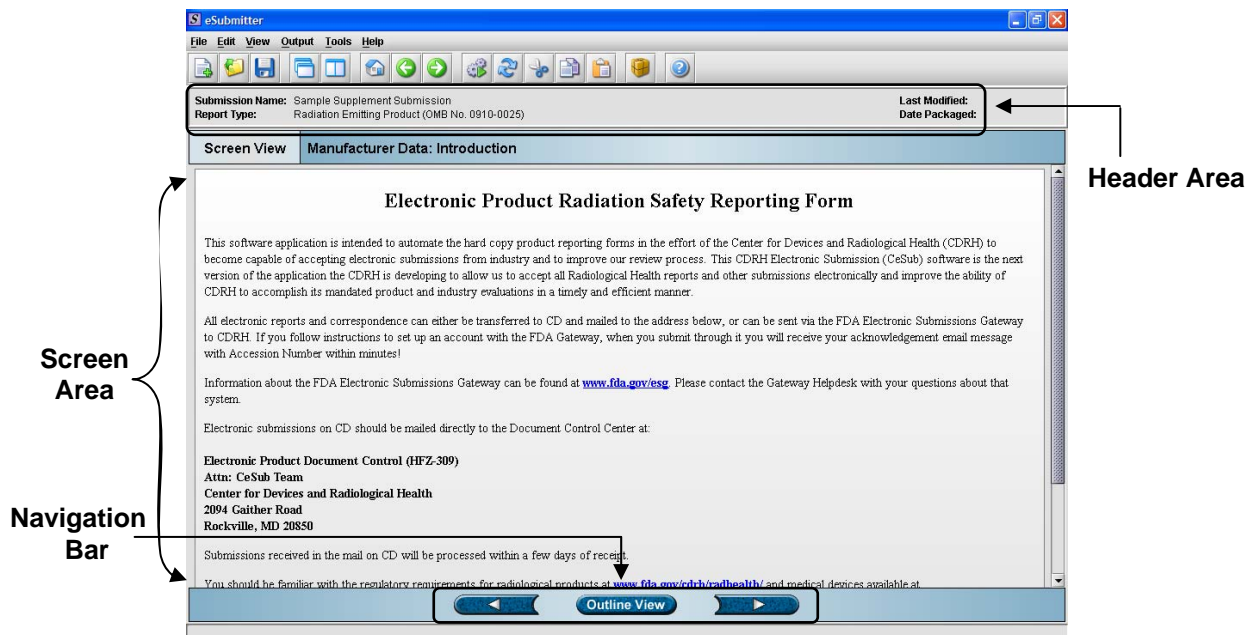
Subsection 3.1: Application Window

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.

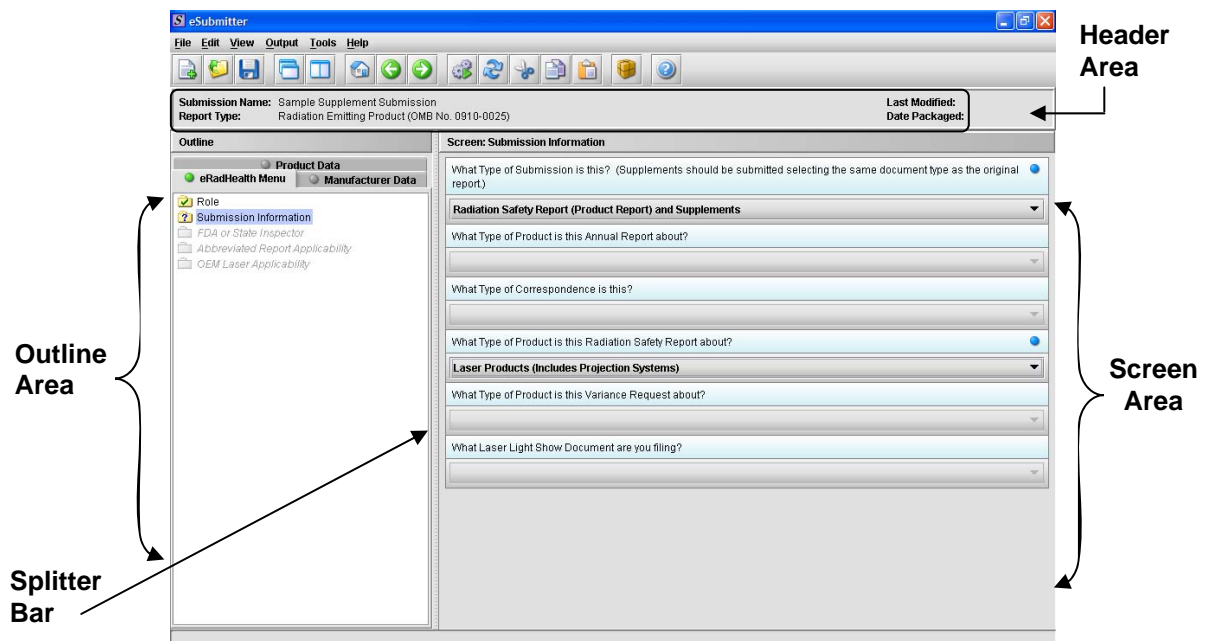


Subsection 3.1: Application Window

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)



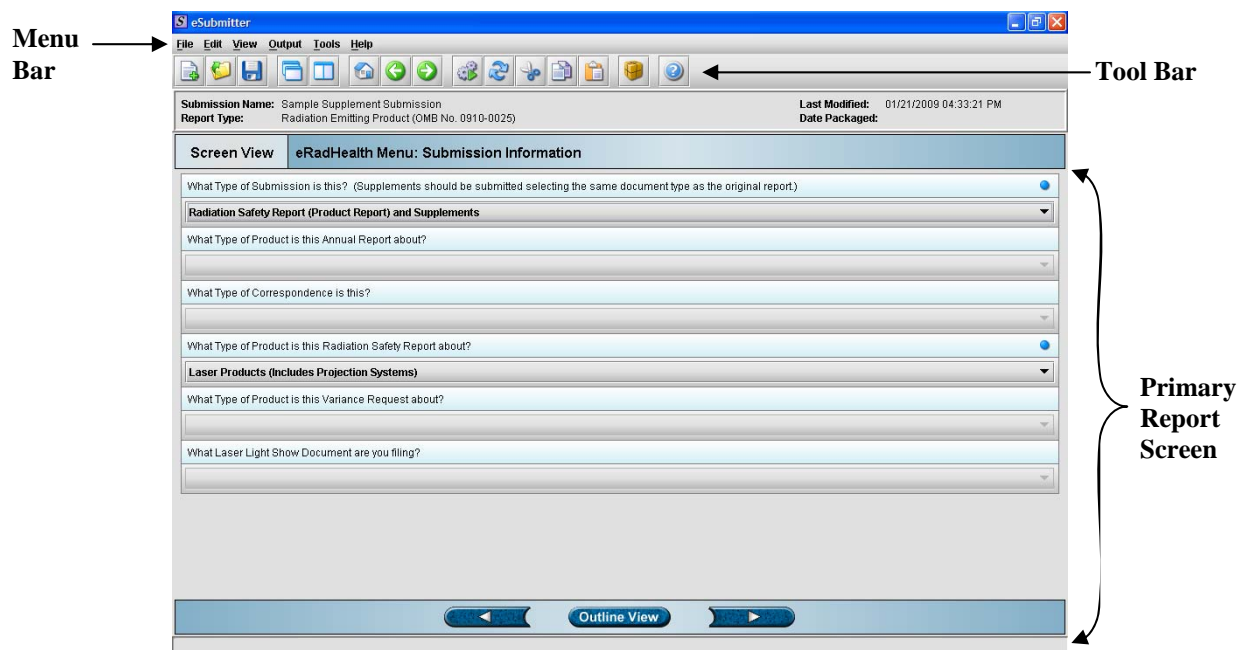
Subsection 3.1: Application Window

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](#).

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:

Continued on Next Page

Subsection 3.1: Application Window

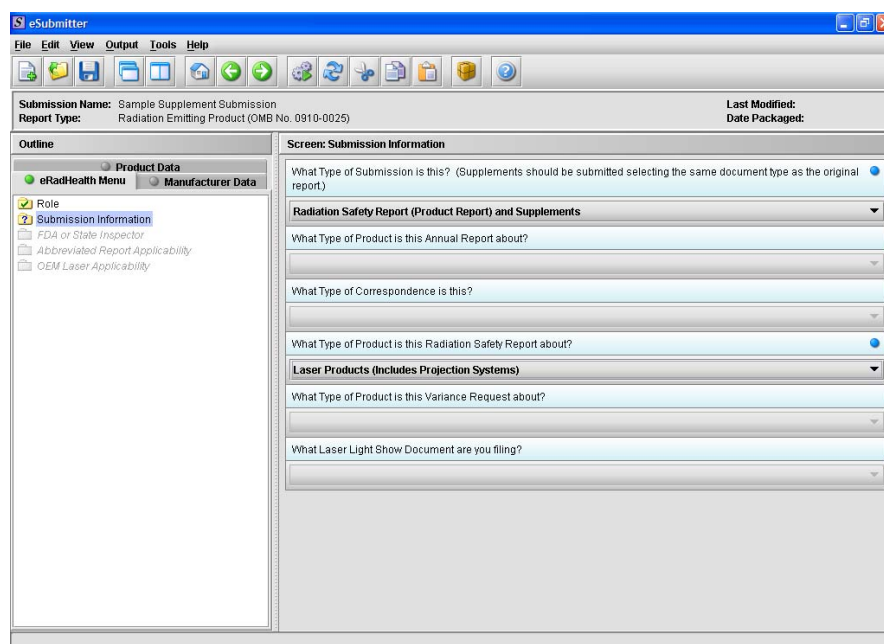
Header Area

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.
- **Packaged Date** – 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.
-

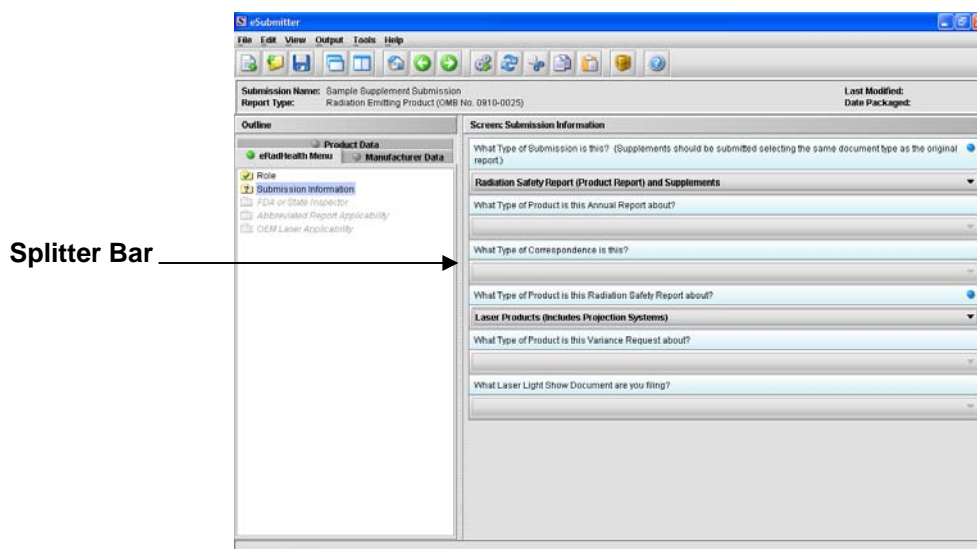
Screen Area/View

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

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 **Tools** and **Output** (with the exception of *Package Files for Submission*) through the actual menus. For information relating to tools and output functions, refer to pages 43 and 98 respectively.

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

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

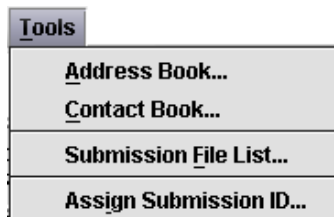
Continued on Next Page

Subsection 3.2: Toolbar

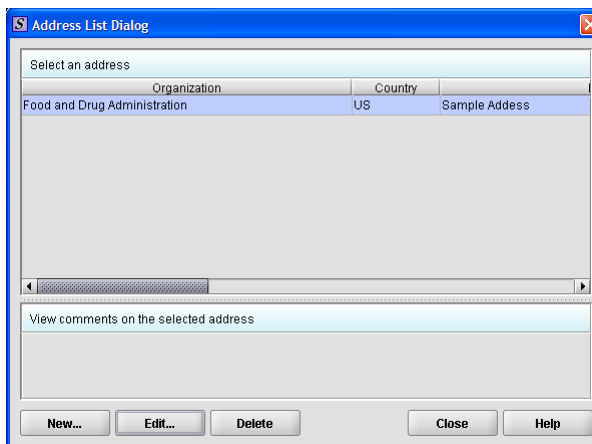
	Previous – Navigates to the previous screen.
	Next – Navigates to the next screen.
	Process Screen Changes – Processes your changes to screens without saving the template or selecting another node. This option allows you to see how rules impact the form based on the changes made without having to leave the screen.
	Screen Undo – Undoes most recent changes made.
	Cut – Cuts text.
	Copy – Copies text.
	Paste – Pastes text.
	Package Files for Submission – Packages your submission to send to FDA after you have completely answered all required questions. For complete information, see <i>Packaging Submission Files</i> on page 87.
	Help Topics – Displays the Help Menu.

Subsection 3.3: Menu Bar - Tools

Introduction Each command on the Tools Menu is described below:



Tool	Function
<p>Address Book</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 (New, Edit, Delete, Close, and Help) in this dialog box are described below:</p>

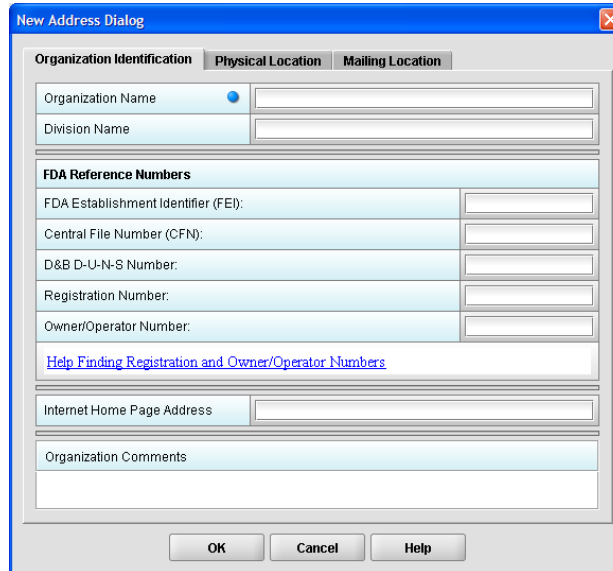


Continued on Next Page

Subsection 3.3: Menu Bar - Tools

New

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

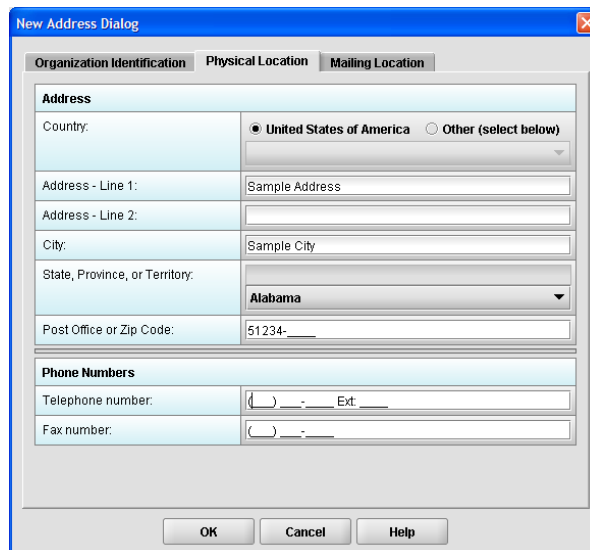


The screenshot shows the 'New Address Dialog' window with the 'Organization Identification' tab selected. The dialog has three tabs: 'Organization Identification', 'Physical Location', and 'Mailing Location'. The 'Organization Identification' tab contains the following fields:

- Organization Name (with a blue dot icon)
- Division Name
- FDA Reference Numbers section:
 - 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 (text area)

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

⇒ 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 section:
 - Country: United States of America Other (select below)
 - Address - Line 1: Sample Address
 - Address - Line 2:
 - City: Sample City
 - State, Province, or Territory: Alabama
 - Post Office or Zip Code: 51234-
- Phone Numbers section:
 - Telephone number: () - . Ext. -
 - Fax number: () - .

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

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

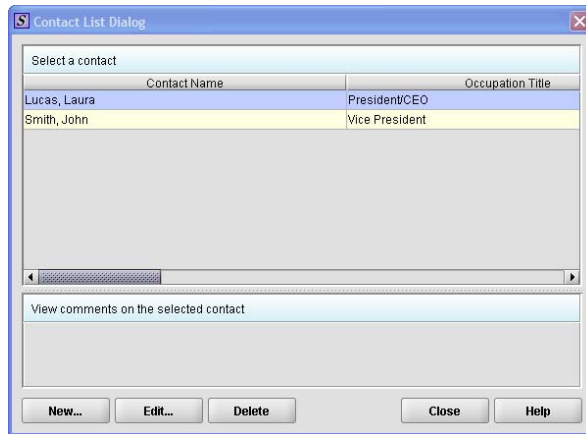
Subsection 3.3: Menu Bar - Tools

	<p>⇒ Click  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.</p> <p>⇒ When you are finished with the addresses, click  to save your edits. Click  to ignore all edits or  to see help text. You return to the <i>Address List Dialog</i> box.</p>
Edit	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.)
Delete	Deletes the selected address from the list.
Close	Closes the dialog box.
Help	Displays the help window with text.

c

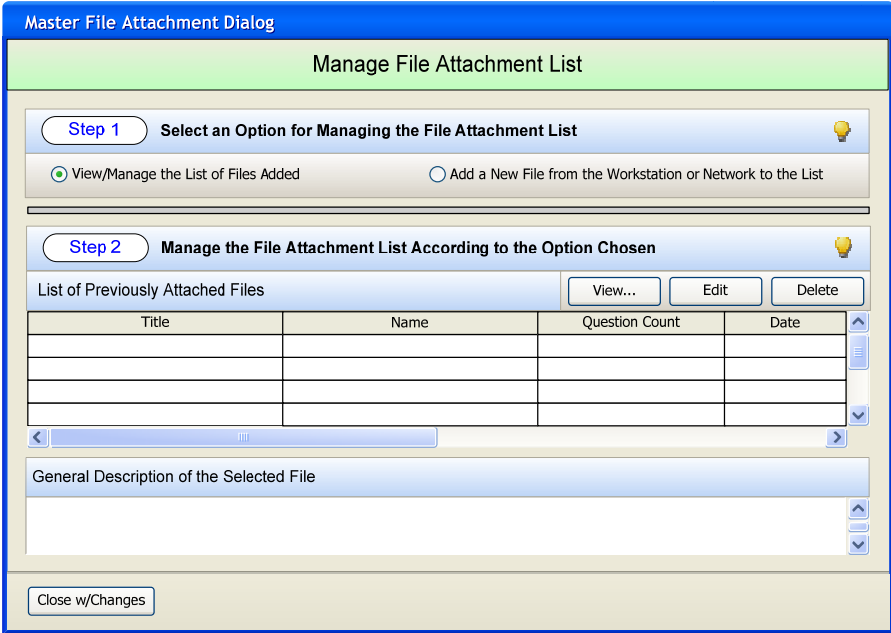
Subsection 3.3: Menu Bar - Tools

Tool	Function
<p>Contact Book</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 on the 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>



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

Subsection 3.3: Menu Bar - Tools

Tool	Function
<p>Submission File List</p>	<p>Displays the <i>Master File Attachment Dialog</i> box, which allows you to manage the file information to be attached for use across questions in the submission.</p>  <p>Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). If you did not set your file viewer under User Preferences, the first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 25.</p> <p>Note: The file list is specific to the submission that is currently open.</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"> • Descriptive title • Physical file name • Number of questions that currently reference the file as an

Subsection 3.3: Menu Bar - Tools

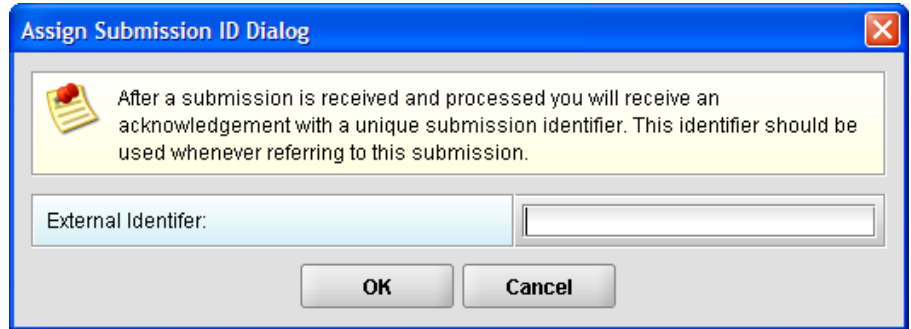
	<p>attachment</p> <ul style="list-style-type: none"> • File date • File size • Path to the file location <p>The options provided in the dialog box are described below:</p>
--	--

Add a New File	Allows you to add a new file to the Master File Attachment list for later use as a question response. For instructions on how to attach files as a question response, see How to Attach a File to an Attachment Question Type , beginning on page 60.
View/Manage File List	Allows you to manage the existing documents in the list of files displayed in Step 2. The options available for managing the list of existing files include View, Edit, Delete, and Close. These options are described below.
View	Displays the selected file within the specified PDF viewer.
Edit	Displays the <i>Edit File Dialog</i> box, which allows the selected file title and general description to be changed.
Delete	Deletes the selected file from the list.
Close w/ Changes	Closes the dialog box and saves the changes made to the <i>Master File Attachment</i> list.

Tool	Function
Assign Submission ID	<p>Allows you to enter an FDA-related identifier to a submission. After you have sent the submission to the FDA for processing and 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>To enter a Report ID:</p> <ul style="list-style-type: none"> ⇒ Select Assign Submission ID from Tools on the Menu bar. You see the <i>Assign Submission ID dialog</i> box (see below). ⇒ Enter the unique identifier assigned by FDA.

Subsection 3.3: Menu Bar - Tools

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



Section 4: Preparing a Submission

Contents

This section contains the following topics:

Topic	See Page
Entering Submission Information	51
Question Types	50
▶ Address and Contact Information	51
▶ Option Lists	54
▶ File Attachments	57
▶ Guidance Documents	64
▶ Text Fields and Messages	67
▶ Product Codes	69
▶ Standards	75
▶ Sections as Tables	77
Saving Submission Entries or Changes	80
Completing a Submission	81

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 35. You should 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.

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 11.	
2.	Navigate through the submission as follows: <ul style="list-style-type: none">If you are in the simple layout, use the buttons on the navigation bar to advance to next/return to previous screen.If you are in the expert layout, use the outline pane, and activate each section to load the screen or the navigation arrows located on the tool bar.	
3.	Provide a response to the question(s) on the screen. The response required depends on the type of question.	

Subsection 4.1: Entering Submission Information

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 4.1.1: Question Types – Address and Contact Information

<p>Address</p>	<p>This question type requires that you enter the address and phone numbers of your organization. You enter the information in text fields and make selections using drop-down menus and clicking option buttons. An example is shown below. Other types of address questions are Contact and Multi-Part Address, which will be discussed below.</p> <div data-bbox="570 661 1357 1171" data-label="Form"> <p>The screenshot shows a form titled "Address" with the following fields: 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, Telephone number (with area code and extension fields), and Fax number. Blue dots are placed to the right of the Country, Address - Line 1, City, State, Province, or Territory, Post Office or Zip Code, Telephone number, and Fax number fields, indicating they are required.</p> </div>
<p>Contact (Simple)</p>	<p>This question type requires that you type contact information (first name, last name, etc.) in text fields. Entries may or may not be required. The figure below shows an example of a simple contact question with the first name, last name, and email address as required fields (as indicated by the blue dots).</p> <div data-bbox="570 1423 1414 1734" data-label="Form"> <p>The screenshot shows a form titled "Contact" with the following fields: Title (Mr., Ms., Dr.), First/Given Name, Middle Name, Last Name, Occupation Title, and Email Address. Blue dots are placed to the right of the First/Given Name, Last Name, and Email Address fields, indicating they are required.</p> </div>
<p>Contact (Multi-Part)</p>	<p>This question type contains multiple sections that you need to complete (indicated by the tabs: Contact Information, Establishment Identification, Physical Location, and Mailing</p>

Subsection 4.1: Entering Submission 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 of these tabs. The "Contact Identification" tab is selected and highlighted. Below the tabs is a form titled "Contact" with the following fields:

Title (Mr., Ms., Dr.):	<input type="text"/>
First/Given Name:	<input type="text"/>
Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>
Occupation Title:	<input type="text"/>
Email Address:	<input type="text"/>

Copy Information from Contact Book into Question

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

Action

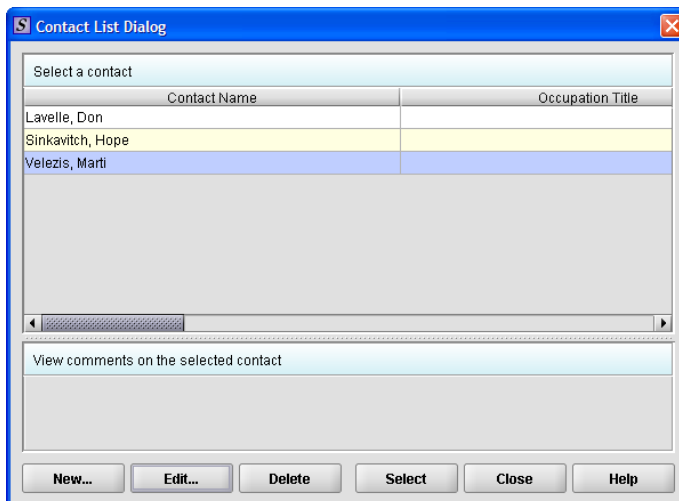
Graphic

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



Subsection 4.1.1: Question Types – Address and Contact Information

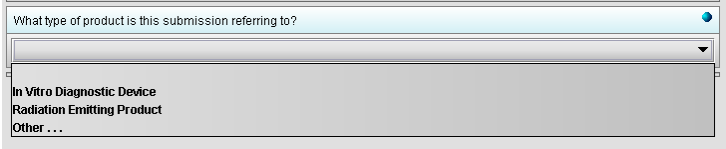

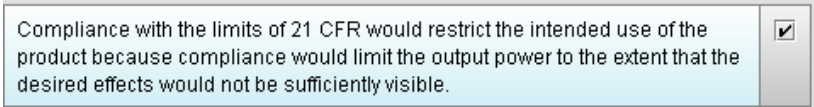
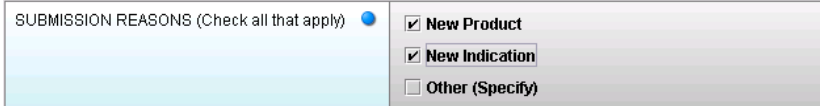
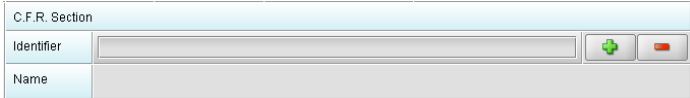
Contact List Dialog Box



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 46.



Subsection 4.1.2: Question Types – Option Lists

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

Subsection 4.1.2: Question Types – Option Lists

Access the List of Available Options

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

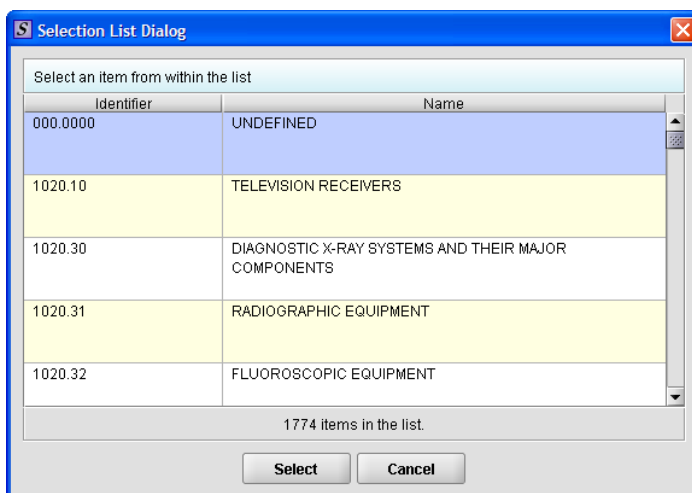
Action

Graphic

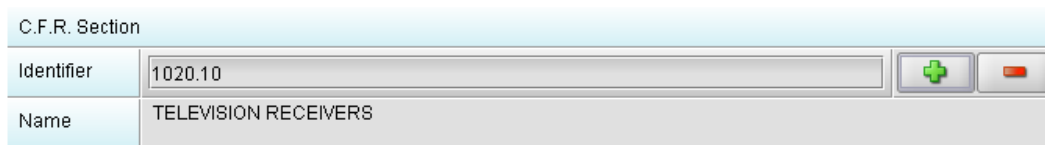
1. Click the **Select Item** icon. A *Selection List Dialog* box is displayed (as shown below).



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.

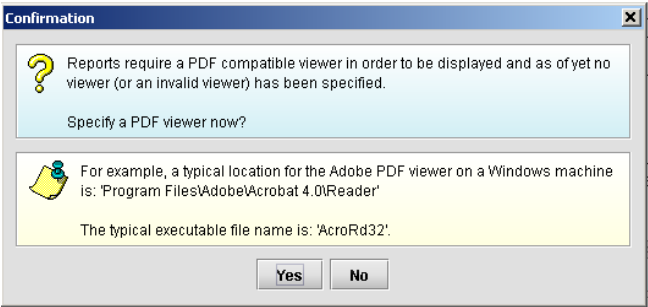


Subsection 4.1.2: Question Types – Option Lists

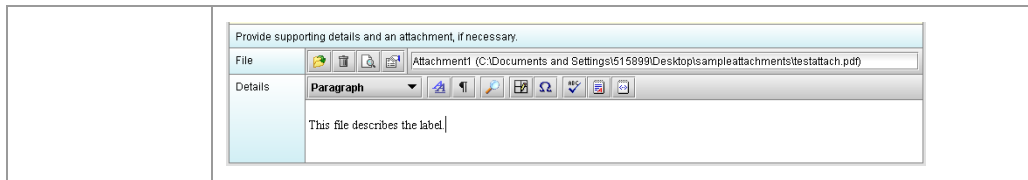
5. Repeat steps 1 through 3 to make another selection.
-

Table	<p>This question type allows you to select from a list or add text items that are then placed in a table. Below is an example. To make selections, click the Add icon ().</p> 
--------------	---

Subsection 4.1.3: Question Types – File Attachments

File Attachment	<p>Please see Section 6 FDA Recommendations for PDF File Specifications to ensure you are meeting the FDA recommendations for electronic files submitted and archived.</p> <p>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 an HTML 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.</p> <p>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).</p> <p>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).</p>  <p>Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 25.</p> <p>Below is an example of a file attachment question with a response properly attached. See instructions for correctly attaching files in the subsequent section.</p>
------------------------	---

Subsection 4.1.3: Question Types – File Attachments



How to Attach a File to an Attachment Question Type

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

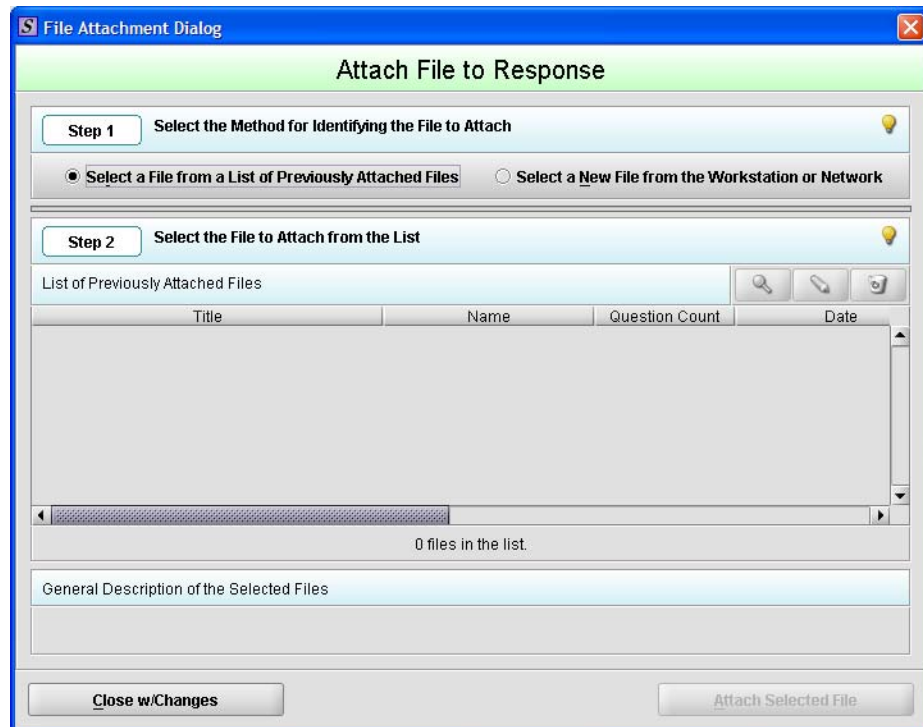
Action

Graphic

1. Click the **Add File** icon to select the desired file to attach as the question response. The *File Attachment Dialog* box 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

Subsection 4.1.3: Question Types – File Attachments

the file to attach. The options are:

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

OR

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

Note: The wizard defaults to the method “Select a File from a List of Previously Attached Files” if the master file list contains any files to choose from. If there are no files in the master file list, it will default to the method “Select a New File from the Workstation or Network”. If you would like to navigate to a location on your computer and select a new file, click the radio button to change the response in Step 1 to “Select a New File from the Workstation or Network”.

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

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

Select a File from a List of Previously Attached Files

Title	Name	Question Count	Date
Sample Attachment	Sample_Attachment_1.pdf	1	08/08/2005 05:21:44

1 file in the list.

Continued on Next Page

Subsection 4.1.3: Question Types – File Attachments

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



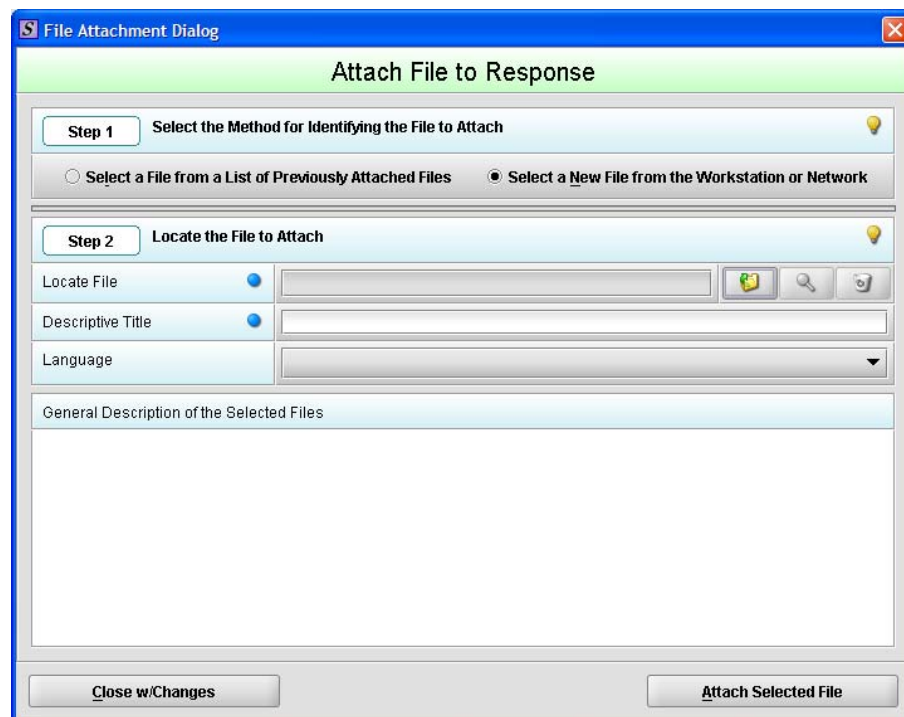
Click the **Attach Selected File** button to properly attach the selected file to the question response.

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

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

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

Select a New File from the Workstation or Network



The screenshot shows a dialog box titled "File Attachment Dialog" with a sub-header "Attach File to Response". It is divided into two steps:

- Step 1: Select the Method for Identifying the File to Attach**
 - Select a File from a List of Previously Attached Files
 - Select a New File from the Workstation or Network
- Step 2: Locate the File to Attach**
 - Locate File: [Text Field] [Browse] [Cancel]
 - Descriptive Title: [Text Field]
 - Language: [Dropdown Menu]
 - General Description of the Selected Files: [Large Text Area]

Buttons at the bottom: **Close w/Changes** and **Attach Selected File**.

Continued on Next Page

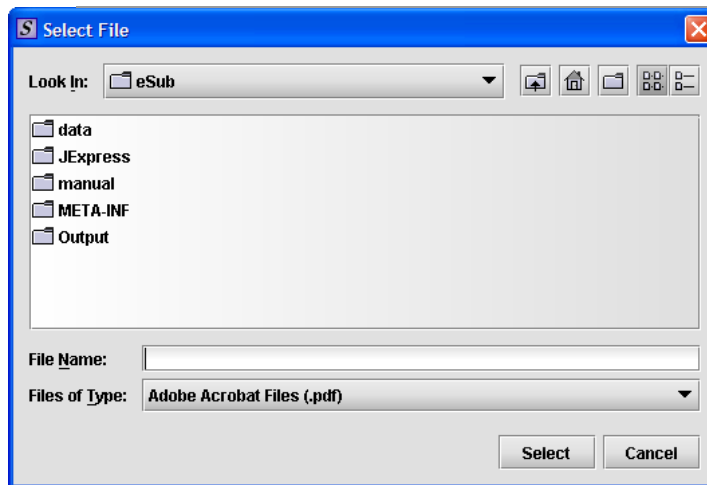
Subsection 4.1.3: Question Types – File Attachments

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.

**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)**.

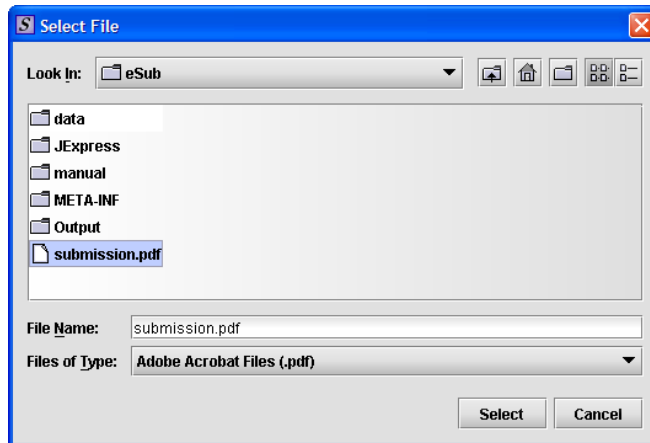
Note: The **Files of Type** drop-down field may not be enabled if the question has been set to restrict the response to only allow a particular file type (e.g., PDF only).

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).

Continued on Next Page

Subsection 4.1.3: 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.

Select

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.

OK

14. Click **Attach Selected File(s)**. You see the path (location) of the file selected appear in the file attachment question.




Attach Selected File

Multiple File Attachments

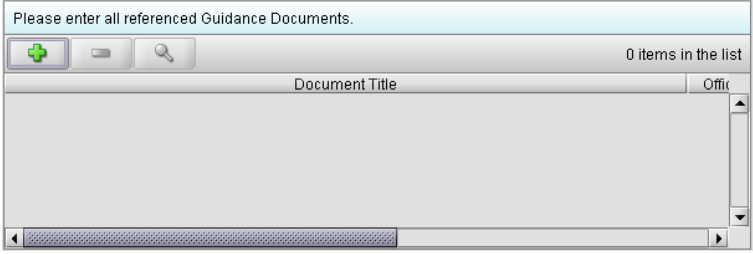
This question type allows you to attach multiple files as a response. Below is an example of an attachment question with a file attachment included. In the image below, the green plus sign is still enabled after attaching a file, indicating that additional files may be attached as the response.

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.

Subsection 4.1.3: Question Types – File Attachments

Attach label(s).		
		
Title	Name	Date
Sample Attachment 1	Sample_Attachment_1.pdf	08/08/2005 05:21:44
Sample Attachment 2	Sample_Attachment_2.pdf	08/02/2005 03:17:6 F

Subsection 4.1.4: Question Types – Guidance Documents

<p>Guidance Documents</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.

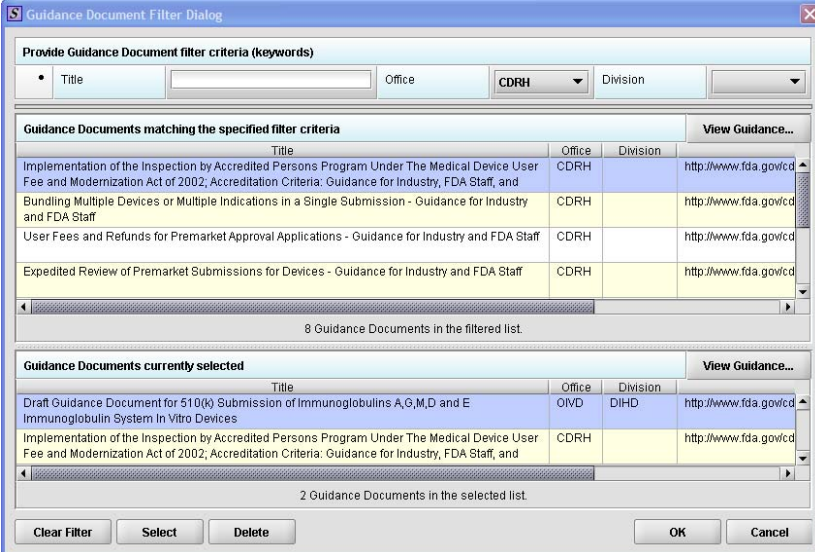
Action

Graphic

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



Guidance Document Filter Dialog Box



Provide Guidance Document filter criteria (keywords)			
Title	Office	CDRH	Division
Guidance Documents matching the specified filter criteria			
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
8 Guidance Documents in the filtered list.			
Guidance Documents currently selected			
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
2 Guidance Documents in the selected list.			

Subsection 4.1.4: Question Types – Guidance Documents

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

Clear Filter

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

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

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

View Guidance...

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

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

Select

Delete

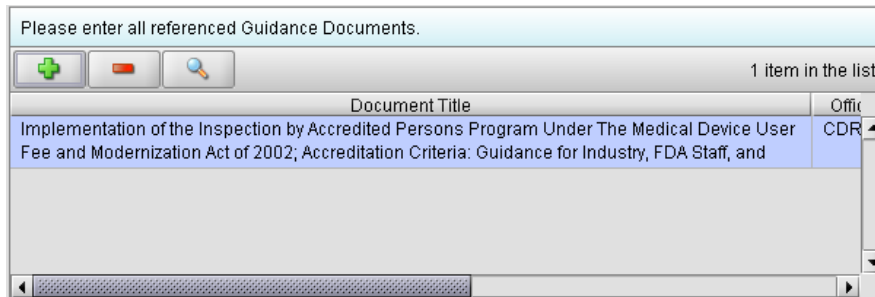
Subsection 4.1.4: Question Types – Guidance Documents

-
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



The screenshot shows a software window titled "Please enter all referenced Guidance Documents." The window has a light blue header bar. Below the header, there 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 "Offic". The table has 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 "Offic" column. The table is scrollable, and there is a scrollbar on the right side.

Document Title	Offic
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





Subsection 4.1.5: Question Types – Text Fields and Messages

<p>Memo (Multi Line Text)</p>	<p>This question type provides an area for you to enter several lines of text (as shown below).</p> <div data-bbox="626 516 1411 688"></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="626 898 1411 1037"></div>
--	---







<p>Text, Single Line</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="570 1255 1398 1297"></div>
---	---

<p>Message</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">• Information Message <div data-bbox="626 1656 1411 1717"></div> <ul style="list-style-type: none">• Error Message
-----------------------	---

Subsection 4.1.4: Question Types – Guidance Documents


	<div data-bbox="630 352 1414 489"> 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: cdrhsub@cdrh.fda.gov. Be sure to include your name, company name and contact information in the email. Thank you again for using our electronic product reporting software.</div> <ul style="list-style-type: none"><li data-bbox="651 527 883 558">• Note Message <div data-bbox="630 590 1414 653"> Contains Information on the Applicable Contacts</div> <ul style="list-style-type: none"><li data-bbox="651 688 1003 720">• Confirmation Message <div data-bbox="630 758 1373 821"> Save the following changes before closing the report template?</div> <ul style="list-style-type: none"><li data-bbox="651 856 943 888">• Warning Message <div data-bbox="630 926 1373 1031"> 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).</div>
--	--

Subsection 4.1.6: Question Types – Product Codes

Product Code (Single)	<p>This question type allows you to search for and then identify the product code that is assigned to your product or device. If applicable, you are able to search for the device class, device panel, and particular CFR section. The response to this question is for a single product code. Below is an example of a product code question.</p> <div style="border: 1px solid gray; padding: 5px;"> <p>Choose the product code for this submission.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">Product Code</td> <td style="width: 30%;"><input type="text"/></td> <td style="width: 10%; text-align: center;"></td> <td style="width: 10%; text-align: center;"></td> </tr> <tr> <td>Product Code Name</td> <td colspan="3"></td> </tr> <tr> <td>Device Class</td> <td colspan="3"></td> </tr> <tr> <td>Classification Panel</td> <td colspan="3"></td> </tr> <tr> <td>C.F.R. Section</td> <td colspan="3"></td> </tr> <tr> <td colspan="4">Add any other product codes that are applicable to this submission.</td> </tr> </table> </div>	Product Code	<input type="text"/>			Product Code Name				Device Class				Classification Panel				C.F.R. Section				Add any other product codes that are applicable to this submission.			
Product Code	<input type="text"/>																								
Product Code Name																									
Device Class																									
Classification Panel																									
C.F.R. Section																									
Add any other product codes that are applicable to this submission.																									


Enter a Three-Letter Code in the Product Code Question

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

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

Search for a Three-Letter Code by Keyword

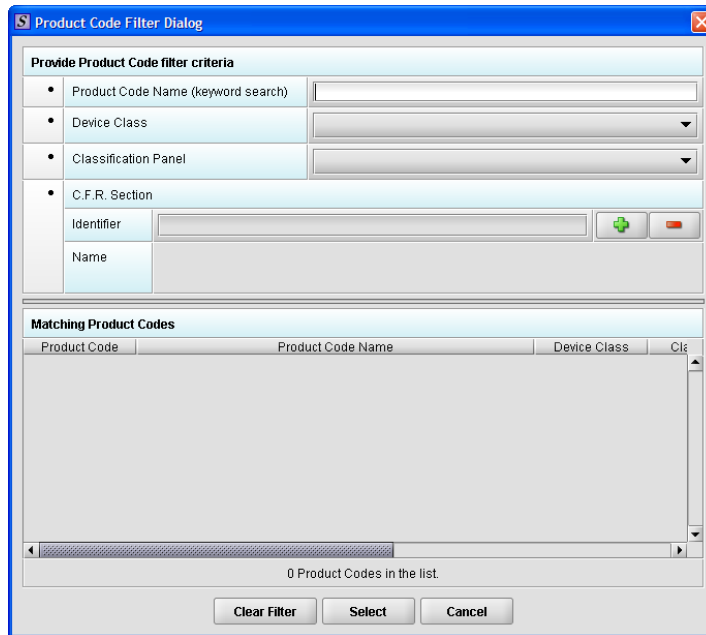
To search for a three-letter code by keyword, follow the instructions below:



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

Continued on Next Page

Subsection 4.1.7: Question Types – Product Codes


Product Code Filter Dialog Box





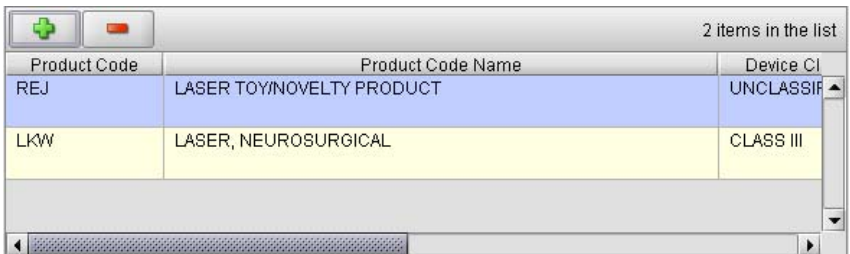
2. Enter a keyword to search the database. You will be provided a list of product codes from which to choose in the **Matching Product Codes** portion of the dialog box.
3. To further refine your search, **if desired**:
 - Click the **Device Class** drop-down list and make a selection.
 - Click the **Classification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

Continued on Next Page

Subsection 4.1.6: 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.

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

Add Product Codes

To add product codes, follow the instructions below:

Action

Graphic

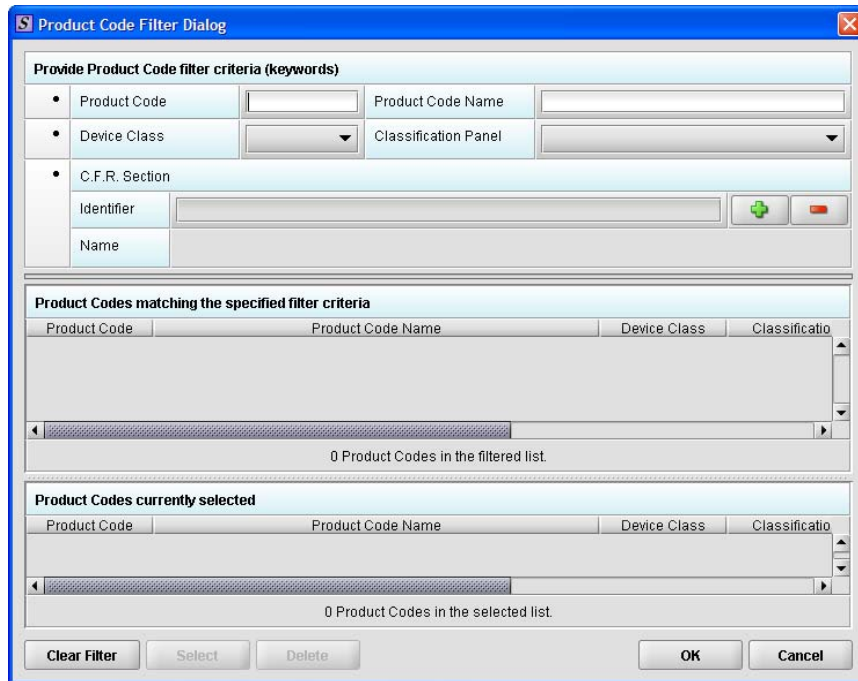
1. Click the **Add Product Code** icon. You see the *Product Codes Filter Dialog* box (as shown below).



Continued on Next Page

Subsection 4.1.7: Question Types – Product Codes

Product Code Filter Dialog Box



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



Enter Multiple Three-Letter Codes in the Product Code Question

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

- | 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). | |

Continued on Next Page

Subsection 4.1.6: 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 HOSE
BRW	PROTECTOR, DENTAL	CLASS I	ANESTHESIOLOGICAL

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 HOSE

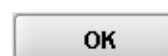
- Repeat steps 1 and 2 to continue to add product codes.

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 for Multiple Three-Letter 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.

Continued on Next Page

Subsection 4.1.7: 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

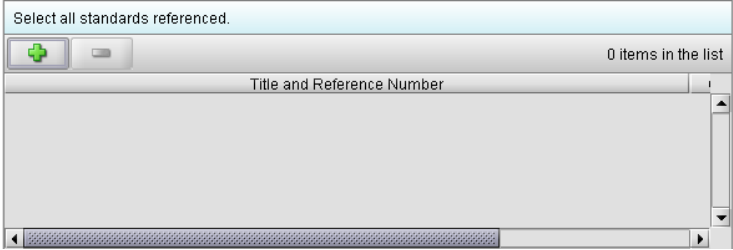
Click **Delete** to remove a product code from the selection.



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



Subsection 4.1.7: Question Types – Standards

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

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

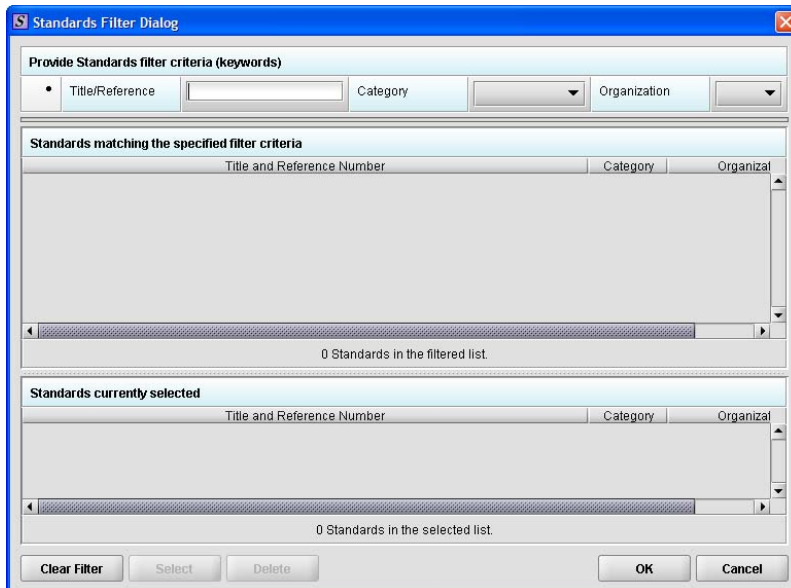
Action

Graphic

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




Standard Filter Dialog Box



2. Enter a title in **Title Reference** (if known) to search the database.

Subsection 4.1.7: 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 4.1.8: Question Types – Sections as Tables

Sections as Tables

Entire sections may appear as a table. This 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).

The screenshot shows a control panel with buttons for 'New', 'Delete', 'Delete All', an up arrow, and a down arrow. Below these are 'List' and 'Details' tabs. The 'List' tab is active, displaying a table titled 'List of Sites' with the following data:

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

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

The screenshot shows the same control panel as above, but the 'Details' tab is active. It displays a form titled 'Details of Selected Site' with the following fields:

- Status of Change: A dropdown menu with a blue dot indicator.
- Site Operation: A list of three items, each with a blue dot indicator and a dropdown menu:
 - Manufacturer
 - Contract Manufacturer
 - Contract Sterilizer

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


Subsection 4.2: 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 19.

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:

Action	Graphic
1. Click File > Save .	
OR	
Click the Save icon on the tool bar.	
If you do not finish entering information into a submission in one session, you may return to it at another time. See <i>Reopening an Existing Submission</i> on page 34.	
2. If you wish to close the submission, click File > Close . The <i>Intro Screen</i> is then displayed.	

Subsection 4.3: 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 HTML and require an application capable of viewing HTML output, such as a WEB browser, the full version of Adobe Acrobat (not Acrobat Reader), or Microsoft Word.

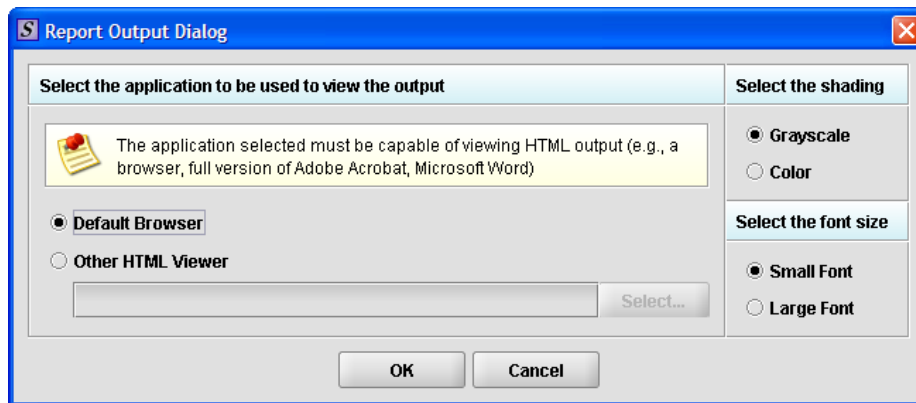
To determine if required data is missing from the submission:

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



Continued on Next Page

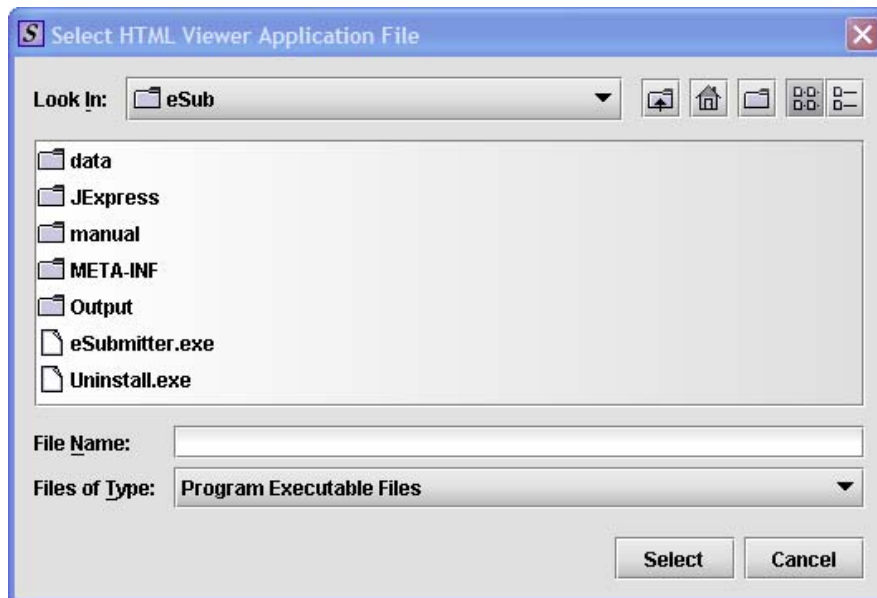
Subsection 4.3: Completing a Submission

2. On this dialog box:
 - Select the desired application to view the output in HTML:
 - 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



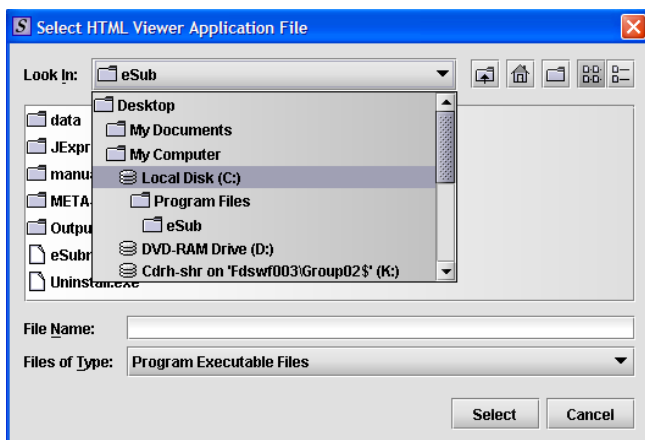
Continued on Next Page

Subsection 4.3: Completing a Submission

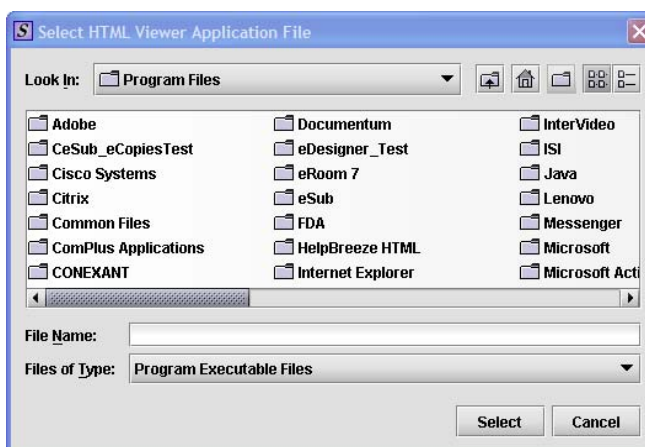
3.
 - Click in the **Look In** box to navigate to the **executable (.EXE)** of the application to view the HTML. For example, if you want to view the missing data output report in Word 2002, you would navigate using the following path:

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

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

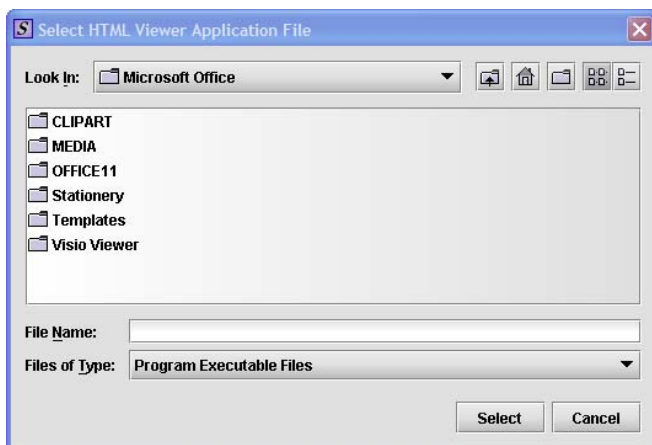


Finding Word's Executable File (Navigation 1)

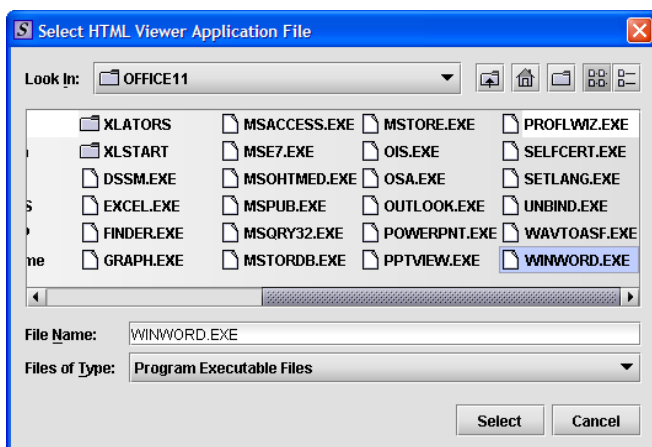


Finding Word's Executable File (Navigation 2)

Subsection 4.3: Completing a Submission



Finding Word's Executable File (Navigation 3)



Finding Word's Executable File (Navigation 4)

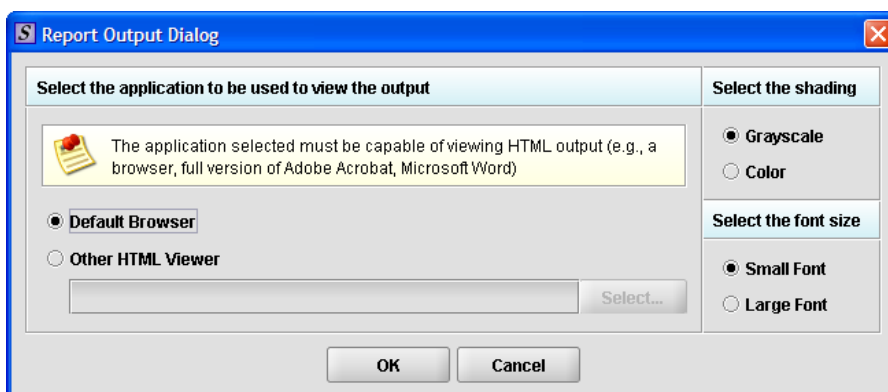
4. Click **Select**. You return to the *Report Output Dialog* box with your selection showing (as shown below).



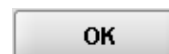
Continued on Next Page

Subsection 4.3: Completing a Submission

Report Output Dialog Box

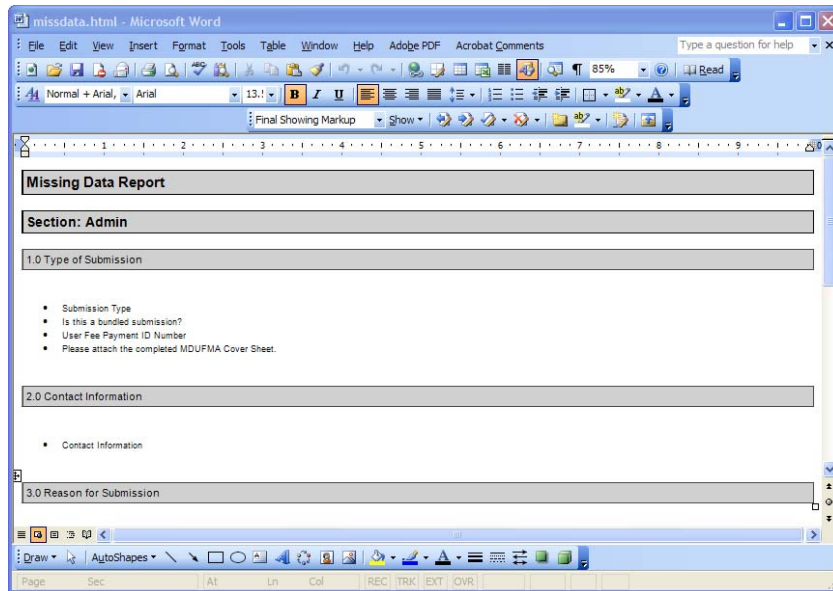


5. Select the desired shading of the report: click the radio button for either **Grayscale** or **Color**.
6. Select the desired font size: click the radio button for either **Small Font** or **Large Font** (which is approximately 10 pt).
7. When you are finished making selections, click **OK**. The eSubmitter software generates the report in HTML, 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.



Continued on Next Page

Subsection 4.3: Completing a Submission



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

Subsection 4.3.1: 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.

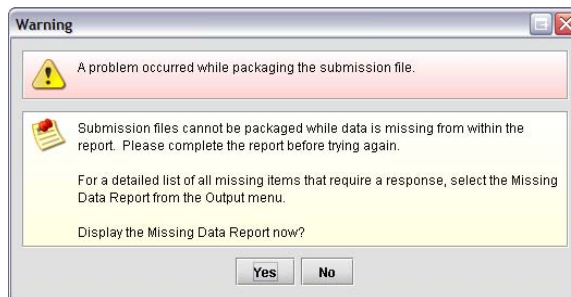
Action

Graphic

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

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

Warning

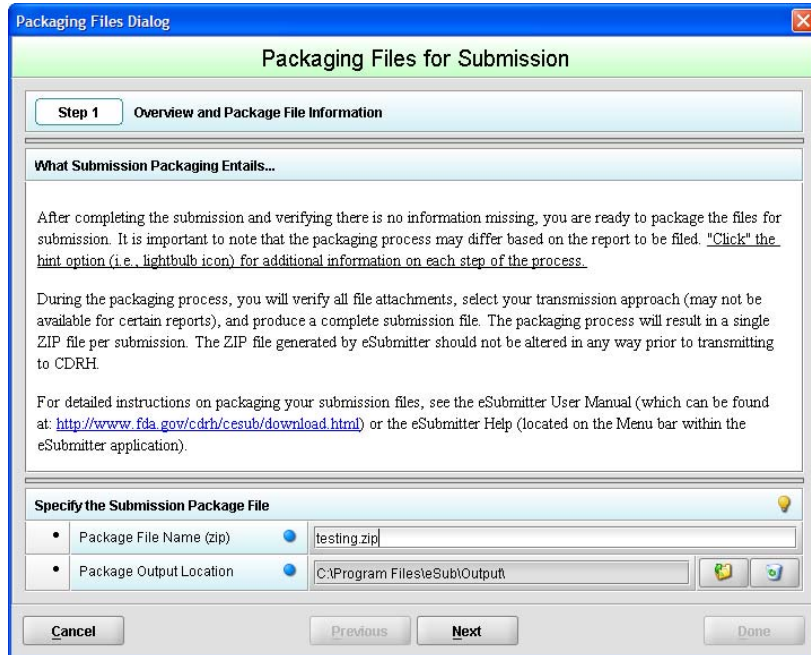


3. If the submission has all required data, the *Packaging Files Dialog* box is displayed (as shown below). Within the *Packaging Files Dialog* box you will be prompted to move through a series of steps detailed below.

Continued on Next Page

Subsection 4.3.1: 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.

Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

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

Specify the Submission Package File	
• Package File Name (zip)	testing.zip
• Package Output Location	C:\Program Files\Sub\Output

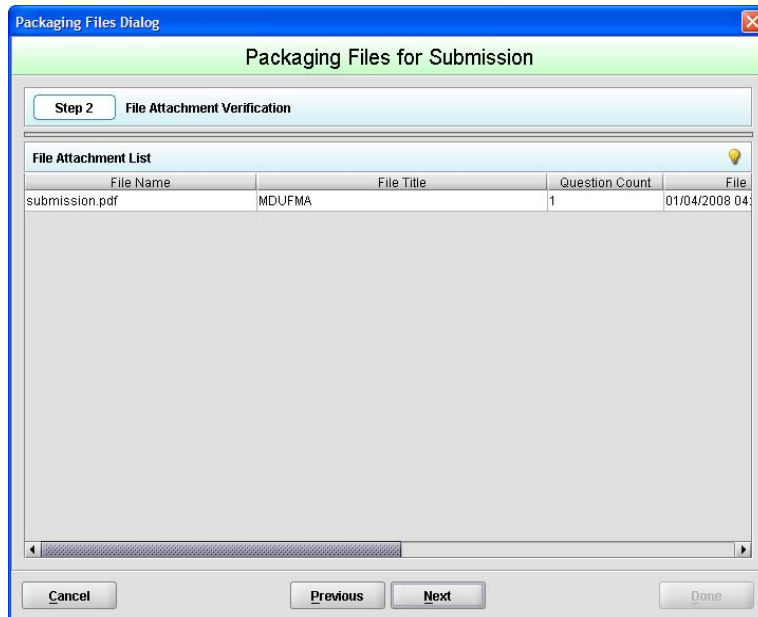
3. Click **Next** to proceed to *Step 2: File Attachment Verification*.

Next

Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

Step 2: File Attachment Verification



This section lists all file attachments used in the submission.

Action

Graphic

1. Check the list to ensure that all of the appropriate file attachments are listed (only files referenced in responses will be included). See above for an example.
2. Check the question counts to confirm that the files are attached.
 - > **NOTE:** If a file appears to be missing from the list, go to the **Submission File List** within eSubmitter (File Menu > Tools > Submission File List). In the **Master File List**, ensure that each file is attached to a question. A zero in the Question Count column indicates that the file is not attached to a specific question and therefore will not be included in the packaged submission.

Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

-
3. Check the file dates, size, and locations to ensure the correct versions of the files are provided.
 4. Click **Next** to proceed to **Step 3** and continue packaging the submission.



OR

Click **Previous** to go back to **Step 1**.



OR

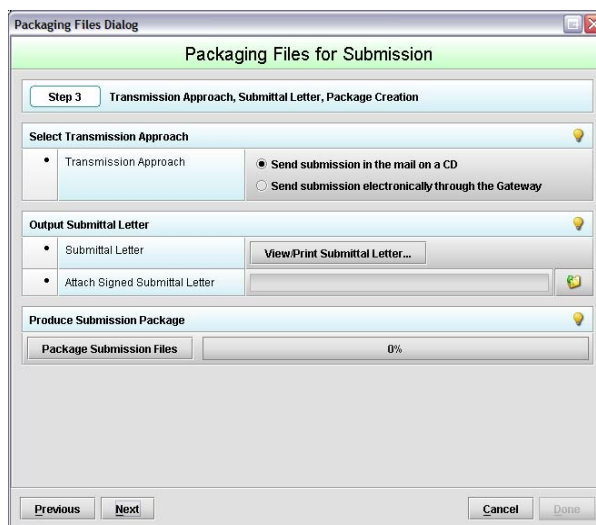
Cancel and exit the *Package File Dialog* box.



Step 3: Transmission Approach, Submittal Letter, and Packaging

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**.



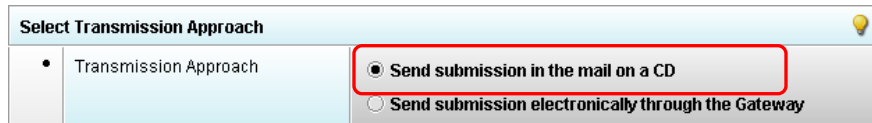
Continued on Next Page

Subsection 4.3.1: 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.

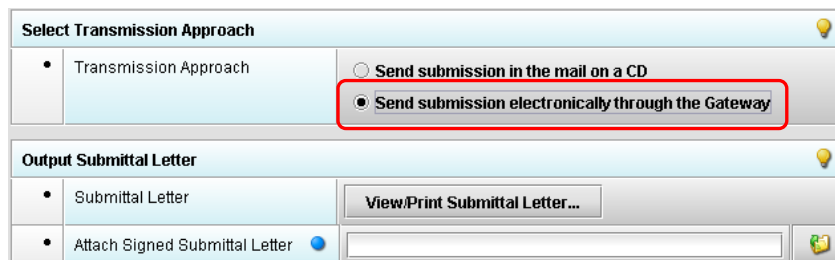


Select Transmission Approach	
• Transmission Approach	<input checked="" type="radio"/> Send submission in the mail on a CD <input type="radio"/> Send submission electronically through the Gateway

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

NOTE: If you plan to send your submission through the ESG, you will need to register to use the ESG and set up an account. Please see <http://www.fda.gov/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).



Select Transmission Approach	
• Transmission Approach	<input type="radio"/> Send submission in the mail on a CD <input checked="" type="radio"/> Send submission electronically through the Gateway

Output Submittal Letter	
• Submittal Letter	View/Print Submittal Letter...
• Attach Signed Submittal Letter	<input type="text"/>

Output Submittal
Letter (may or
may not be
applicable)

Follow the instructions below for the Output Submittal Letter.

Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

Action	Graphic
--------	---------

1. Click the  button, as shown below.



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

OR

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

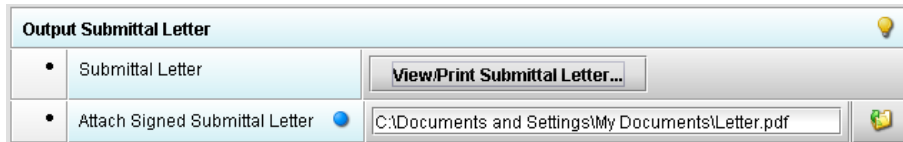
3. Click on the **folder** icon (see below) to attach the signed submittal letter that has been scanned.



Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

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



Produce Submission Package (Always available)

To produce a submission package, follow the instructions below.

Action

Graphic

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



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



Continued on Next Page

Subsection 4.3.1: 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

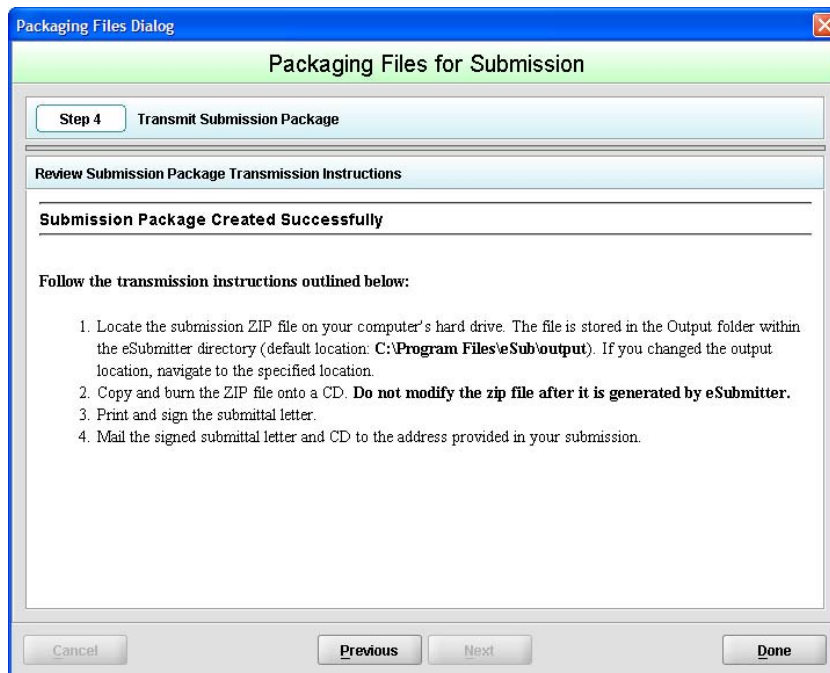
This section provides confirmation that the submission files have been successfully packaged. The submission is ready to be sent to FDA. Follow the instructions below.

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



Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

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



OR

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



Printing, Locating, and Copying Files

The following instructions do not apply if you are transmitting your submission via the Electronic Submissions Gateway. Please see <http://www.fda.gov/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

Graphic

-
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:)**.
-

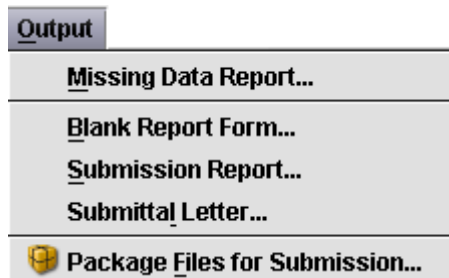
Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

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.
 4. Navigate to and double-click on the **eSub** file folder to open.
 5. Double-click on the **output** file folder to open. The zip file that you created in *Packaging Submission Files* appears. **Do not modify the zip file after it is generated by eSubmitter.**
 6. Copy this file onto a CD.
 7. Mail the CD and signed cover letter to the address provided in your submission.
-

Subsection 5: 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 81.



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

Output Menu Commands

Each command on the Output menu is described below.

Tool	Function
Missing Data Report	Provides a list of required questions that you have not yet answered. The list is provided in HTML 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>Completing a Submission</i> on page 81.
Blank Report Form	Views/prints a blank submission form in HTML.
Submission Report	Views/prints out the submission report with your entries in HTML.
Submittal Letter	Provides a formatted cover letter in HTML 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.

Section 6: 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.

Continued on Next Page

Section 6: FDA Recommended PDF File Specifications

PDF Area	Recommended PDF Specification
Version	The PDF files must be compatible with Adobe Acrobat 5.0 or greater without the use of additional plug-ins other than those provide by Adobe as part of Acrobat. We should not need any additional software to read and navigate the PDF files. There are features in Adobe Acrobat 8.0 that cannot be supported. If you would like to submit Adobe Acrobat 8.0 files, please contact technical support at esubmitter@fda.hhs.gov to ensure you do not use a feature that is unsupported.
Plug Ins	It is acceptable to use plug-ins to assist in the creation of a submission. However, the review of the submission should not require the use of any plug-ins other than any provided by Adobe as part of Acrobat, and must be compatible with Adobe Acrobat 5.0 or greater.
Page Size and Margins	The print area for pages should fit on a sheet of paper that is 8.5 inches by 11 inches. You should allow a margin of at least 1.5 inch on the left margin and 1 inch on all other sides to avoid obscuring information if the pages are subsequently printed and bound.
Page Orientation	Pages should be properly oriented. For example, you should set the page orientation of landscape pages to landscape prior to saving the PDF document in final form to ensure correct page presentation. Landscape pages (including tables) should be oriented such that the header and footer of the document align with the right edge of the page.
Fonts	<p>PDF viewing software automatically substitutes a font to display text if the font used to create the text is unavailable on the reviewer’s computer. Font substitution can affect a document’s appearance and structure, and in some cases it can affect the information conveyed by a document. We cannot guarantee the availability of any one font. Therefore, you should embed all fonts you are using in the PDF files to ensure that those fonts will always be available to the reviewer. When embedding fonts, all characters for the font should be embedded (not just a subset of the fonts being used in the document). One problem associated with embedding fonts is that embedding requires additional computer storage space. Three techniques to help limit the storage space taken by embedding fonts:</p> <ul style="list-style-type: none"> • Limit the number of fonts used in each document • Use only True Type or Adobe Type 1 fonts • Avoid customized fonts. <p>Resizing a document because the contents are too small to read is inefficient. 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 6: FDA Recommended PDF File Specifications

	<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>
Page Numbering	<p>If a submission includes more than one document, you need not provide pagination for the entire submission. Include page numbers only for individual documents.</p> <p>It is easier to navigate 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>
File Size	<p>An electronic submission can have one or multiple file attachments. There is not a limitation of the total size of the submission, but each file should be limited to 50MB in file size. There are several ways to compress file size, including but not limited to: performing Optical Character Recognition, reducing file size in Adobe and creating logical section breaks.</p> <p>If you have questions about file size, please contact technical support at esubmitter@fda.hhs.gov to ensure the file size is acceptable.</p>
Document Properties: Description Tab	<p>Document properties are used to search for individual documents and to identify the document when found. To modify document properties, from the tool bar navigate to File Document Properties.</p>
Document Properties: Initial View Tab	<p>In the Document Properties box, the Initial View tab can also be found. In the Document Options section, all PDF files should set the Show field as Bookmarks Panel and Page. If there are no bookmarks, set the initial view as Page only. Set the Page Layout and Magnification fields to default.</p>
Document Properties: Security	<p>PDF files are stored as original documents and will not be altered from their original form. Remove any security settings, read-only, or password protection used on the files. Electronic Copies submitted with security settings will not be accepted.</p>
Indexing PDF Documents	<p>Full text indexes are used to help find specific documents and/or to search for text within documents. When a document or group of documents is indexed, all words and numbers in the file and all information stored in the Document Information fields are stored in special index files that are functionally accessible using the search tools available in Acrobat.</p>

Section 6: FDA Recommended PDF File Specifications

	<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>Bookmarks and Hypertext Links</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"> • Use meaningful bookmarks (e.g., the title of the section, name of a study, data set, or facility). This will aid the reviewer in locating information and navigating the submission. • Bookmark references can be created for the heading of a section, subsection or title of figures and tables within the document. In general, including a bookmark to the main table of contents for a submission or item is helpful. Make the bookmark hierarchy identical to the table of contents. • Use hyperlinks within the file. Hyperlinks are used to improve navigation through PDF documents and are encouraged. Hyperlinks can be designated by rectangles using thin lines or by blue text or you can use invisible rectangles for hypertext links in a table of contents to avoid obscuring text. Hyperlinks throughout the body of the document to supporting annotations, related sections, references, appendices, tables, or figures that are not located on the same page are helpful and improve navigation efficiency. When creating bookmarks and hyperlinks, the magnification setting should be set to Inherit Zoom so that the destination page displays at the same magnification level that the reviewer is using for the rest of the document. <p>Important Note: Hyperlinks <u>between</u> individual PDF document files are not currently supported and any absolute links that reference across files will not work.</p> <p>In general, for documents with a table of contents, provide bookmarks and hypertext links for each item listed in the table of contents including all tables, figures, publications, other references, and appendices. These bookmarks and hypertext links are essential for the efficient navigation through documents.</p>
<p>Optical Character Recognition</p>	<p>PDF documents produced by scanning paper documents are usually inferior to those produced from an electronic source document such as MS Word. Scanned documents are more difficult to read and do not allow the reviewers to search or copy and paste text for editing. The use of scanned documents should be</p>

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avoided if at all possible. If scanning cannot be avoided, the following is highly recommended:

- Perform optical character recognition (OCR) on all scanned documents so that the text is searchable
- Check to see that the content has been correctly converted.

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.

For files with images and photographs:

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 50MB for a single file. Consider multiple files for these types of documents.

Note: Scanned tables and graphs cannot be extracted easily if scanned. Most OCR programs will distort the data in tables and graphs. Convert MS Word documents to PDF, as this method usually retains the formatting.

For a paper document with handwritten notes:

Paper documents containing handwritten notes should be scanned at 300 dpi. These handwritten notes should be made in black ink for clarity.

If you have questions about creating electronic copies, please contact technical support at esubmitter@fda.hhs.gov to ensure that the format is acceptable prior to developing your submission.

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Naming PDF Files	<p>We are recommending names for folders and selected files in individual guidances for specific submission types. For uniformity, we hope that you use our specific naming conventions when they are provided. Reviewers are trained to look for these folders and files, and using the recommended names should help avoid misunderstandings, improve communication, and speed the review of a submission.</p> <p>When we do not specify a file name, you can use file names up to 32 characters in length with a 3-character extension. Do not use punctuation, spaces, or other nonalphanumeric symbols in file names when naming the files for attachments. For example, do not use slashes (/ \), tildes (~), asterisks (*), periods (.), brackets [], single quotation marks (‘), double quotation marks (“) or parentheses (). Once the file is attached to a question, it can be selected as an attachment to other questions, if appropriate.</p> <p>The eSubmitter tool supports the following file types:</p> <ul style="list-style-type: none">• Portable Document Format Files (.pdf)• Excel Files (.xls, .csv)• SAS System XPORT Files (.xpt)• Extensible Markup Language Files (.xml, .dtd)• Archive/Compressed Files (.zip)• Standard Generalized Markup Language Files (.sgml)• MDL Molfiles Files (.mol) <p>However, based on the application or report you are submitting, the question(s) may have restrictions on which file types you are allowed to attach. For example, some questions may allow you to attach any of the file types supported by eSubmitter and some may only allow you to attach PDF and Excel files as the questions response or supporting documentation.</p>
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Section 7: User Support

Introduction

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