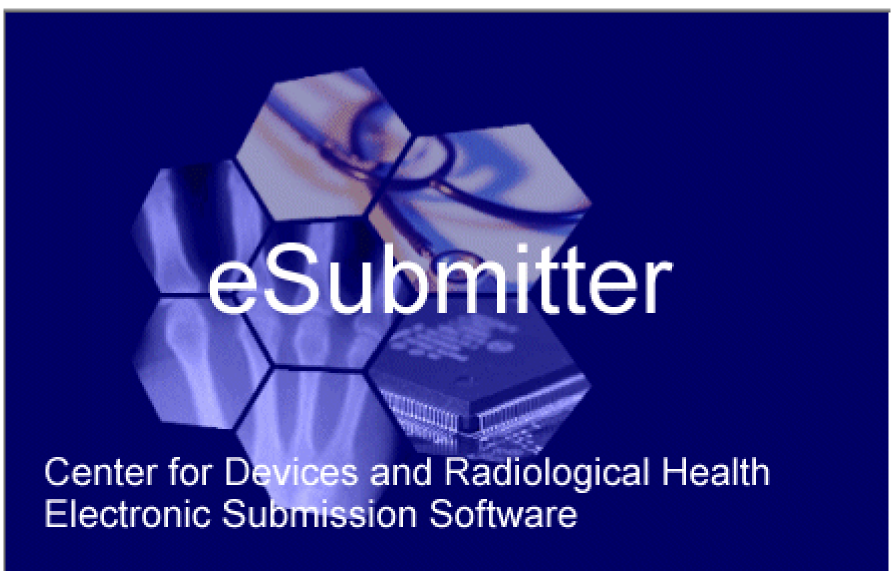
CeSub eSubmitter

Document Version 4.3



Prepared by OITCDRH

January 7, 2008

DOCUMENT HISTORY

Version Number	Date	Description
Version 1.0	May 26, 2004	OIVD Pre-Pilot Release (Software v1.00.00)
Version 1.1	August 27, 2004	Updated to reflect the enhancements incorporated in the Official OIVD Pilot Release (Software v1.00.01)
Version 2.0	March 15, 2005	Updated to reflect enhancements incorporated into the CeSub Pilot Release (software version 1.10). Updated for applicability to OIVD and Radiological Health.
Version 3.0	June 24, 2005	Updated for corrections and additional descriptions. Also updated to reflect the enhancements in Software versions 1.02.00 and 1.03.00.
Version 4.0	October 31, 2005	Updated to reflect the enhancements in software versions 1.04.00 through 1.07.00
Version 4.1	March 2, 2006	Revised the proxy server settings.
Version 4.2	August 7, 2007	Updated the instructions in the Packaging Submission Files section to incorporate the new packaging feature.
Version 4.3	January 7, 2008	Updated the instructions for release 1.28.01 to include link to special instructions for Windows Vista Users.

CeSub eSubmitter

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Section 1: Introduction

Contents

This section contains the following topics:

Subsection 1.1: System Background

Introduction

The Center for Devices and Radiological Health (CDRH) electronic Submission (CeSub) eSubmitter tool is a free program that allows program participants to electronically complete and submit information for a 510(K) device or radiation emitting product to the Office of In Vitro Diagnostic Device Evaluation (OIVD) or Radiological Health. 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 CDRH. The eSubmitter software requires completing a series of questions in electronic forms and allows attaching documents when additional information is needed.

Filing product reports for radiation emitting products is required by law. The CeSub eSubmitter software replicates several of these reporting guides, which have been available in hard copy for decades. If using the eSubmitter software is not desirable, you may continue to complete hard copies of the report, which are available as Adobe Portable Document Format (PDF) and/or Microsoft Word documents at www.fda.gov/cdrh/comp/eprc.html.

Subsection 1.2: About this Guide

Introduction

The instructions in this guide provide detailed information for installing the CeSub 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 guide is organized into seven sections (including this one):

- **Section 1** provides an introduction and explains the requirements for running CeSub 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

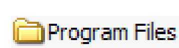
- Windows Operating System
- Adobe Acrobat Reader v5.0 or greater.
- 30 MB of disk space
- Access to a Compact Disk-Recordable drive (CD-R Drive)
- Software capable of viewing HTML, such as a Web browser, Microsoft Word, or Adobe Acrobat (full install version, not the Reader)

Uninstall Instructions

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

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

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

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

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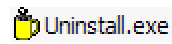
4.	Navigate to and click to open the **eSub** file folder. You will see the folder's contents in the pane on the right-hand side of the screen.	
5.	Double-click on the **Uninstall.exe** file, and follow the instructions provided. **<u>Note:</u>** If you do not see the **Uninstall.exe** file: a. Locate 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 CeSub eSubmitter software. See the following procedure.	

Installation Instructions

CeSub 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

CeSub eSubmitter software is available for downloading from the web at https://www.fda.gov/cdrh/cesub/. To install the latest version of the CDRH CeSub eSubmitter software from this web page, follow the instructions below.

	Action	Graphic
1.	Click the link for Download CeSub eSubmitter Software.	

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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. CeSub eSubmitter has a file locking option that you set to prevent users from accidentally overwriting the work of another. For details, see *Networking* on page 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 CDRH website for the latest information on successfully installing eSubmitter within Windows Vista.

Installation Instructions from a CD-ROM

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

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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: • Open Windows Explorer. • Double-click My Computer to display its contents. • 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. CeSub eSubmitter has a file locking option that you set to prevent users from accidentally overwriting the work of another. For details, see *Networking* on page 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's also located in the **JExpress** subdirectory:

proxyUserName=
proxyPassword=

Section 2: Getting Started

Contents

This section contains the following topics:

Subsection 2.1: Starting the Software

Introduction

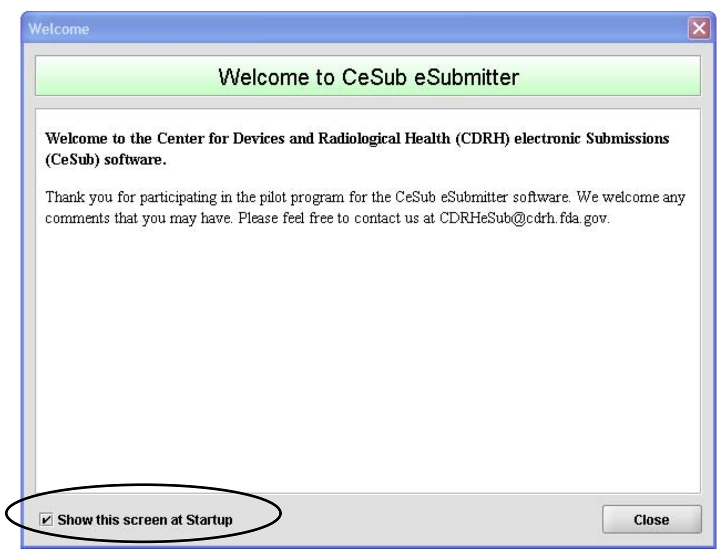
After you have successfully installed the CeSub eSubmitter software, you are ready to start up the application and create a new report.

Starting the Software

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

	Action	Graphic
1.	**Start**, and select **Programs** > **CeSub eSubmitter** > **eSubmitter.**	
2.	You will see a *Welcome dialog box*, which provides an introduction to the application. You can set the *Welcome dialog box* to no longer display at application startup. For this setting, click to clear the **Show this screen at Startup** check box within the dialog box, as shown below.	

Welcome Dialog Box



3.	When you are finished reading the *Welcome dialog box*, click **Close**. You will see an *Alert dialog box* (as shown below).	

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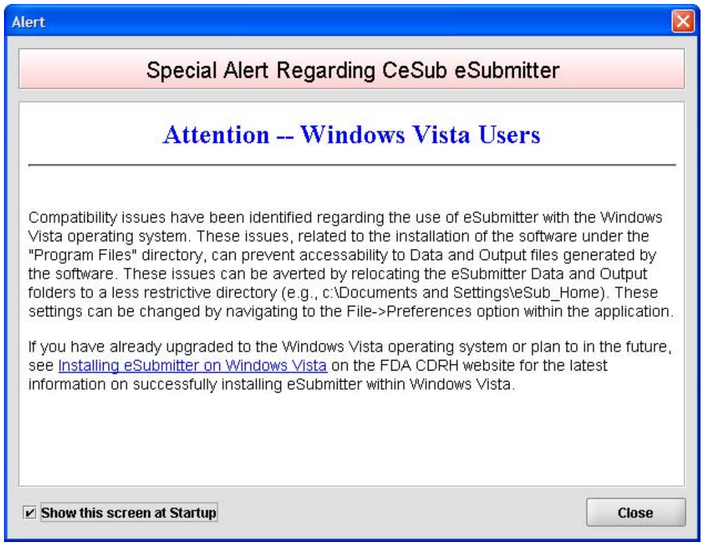
Alert Dialog Box



4. The *Alert dialog box* contains a special alert. Read the information carefully.

   If you have already upgraded to the Windows Vista Operating system or plan to in the future, follow the posted link (http://www.fda.gov/cdrh/cesub/vista.html) for instructions regarding successfully installing eSubmitter within Windows Vista.

5. When you are finished reading the *Alert dialog box*, click **Close**. You will see a *Registration Dialog box* (as shown below).

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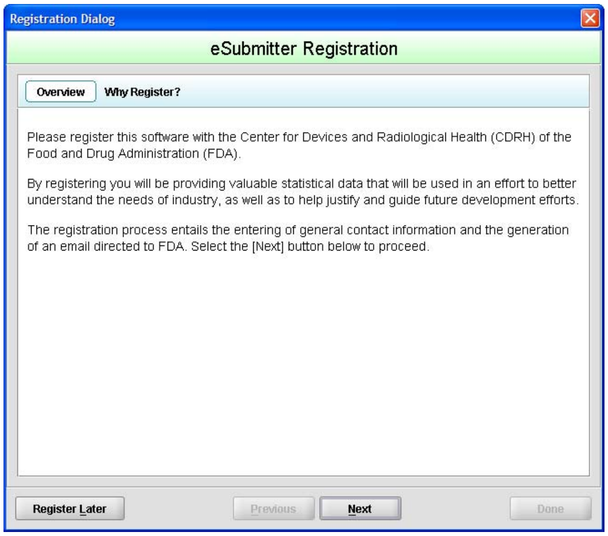
Subsection 2.1: Starting the Software

Registration Dialog Box



6. 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.

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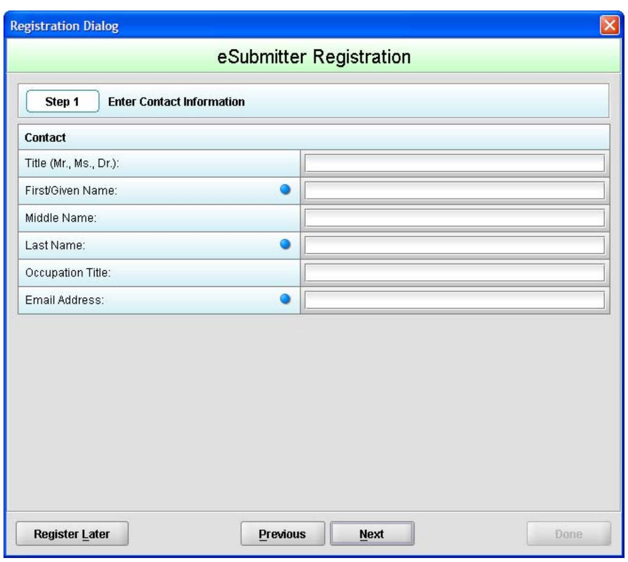
Registration Dialog Box: Contact Information



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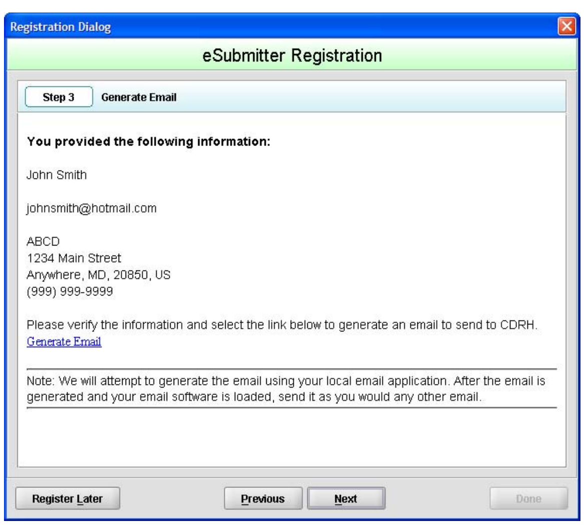
7. On the *Registration Dialog box*, enter the information requested. Required entries are indicated by blue dots. Click **Next**. You see a *Registration Dialog box* asking you to enter address information.

Registration Dialog Box: Address Information

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

Registration Dialog Box: Generate Email



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9. 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.

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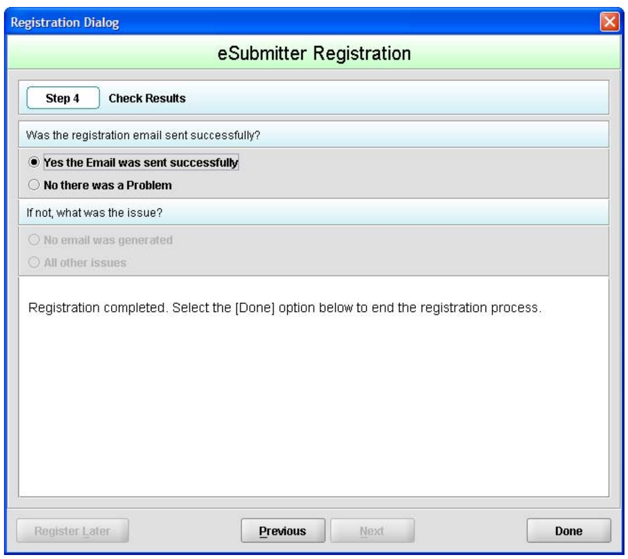
10. Click **Generate Email** in the dialog box. You will see an email.

11. Click **Send** in the email. You see a *Registration Dialog box* to check results.

Registration Dialog Box: Check Results



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

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

14. 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).

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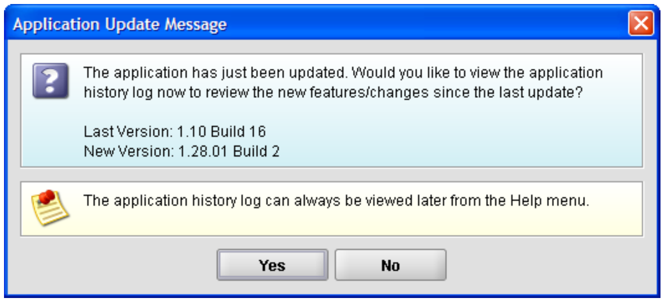
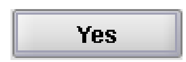
Application Update Message



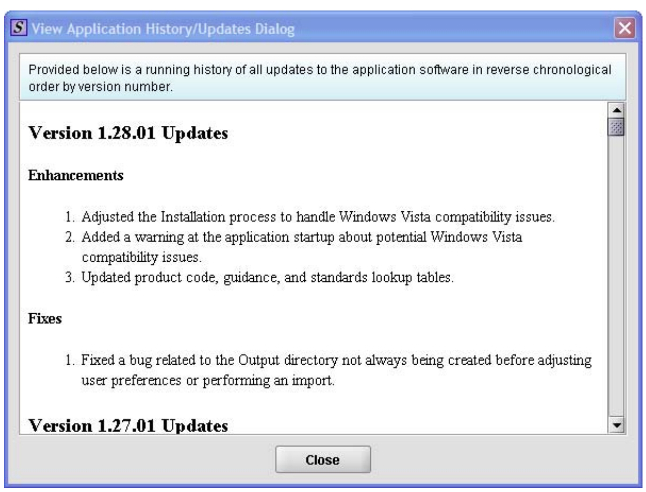
15. On the **Application Update Message**:

- 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).



View Application History/Updates Dialog Box



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

17. Next, you will see the *Open Report Data Dialog box*.

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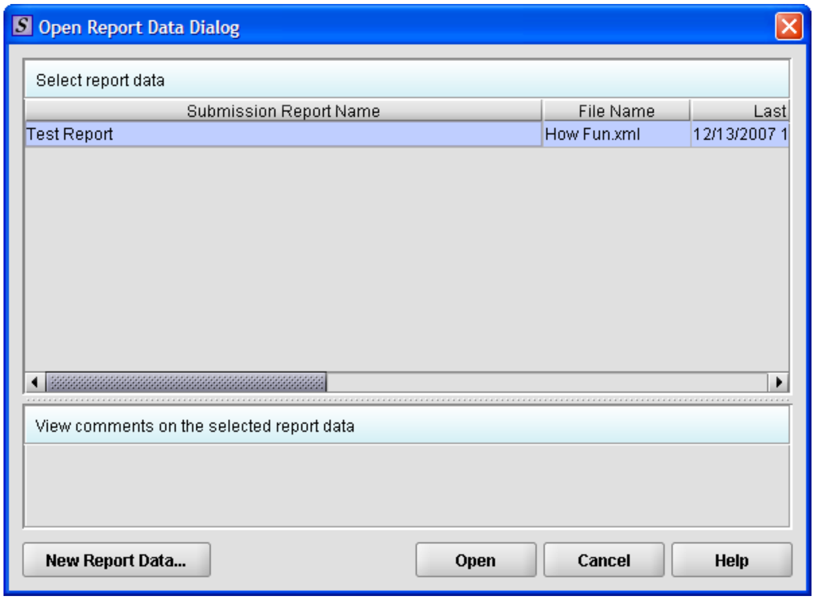
Open Report Data Dialog Box



18. This dialog box allows you to select an existing submission or begin a new one. As you create new reports, they are shown in this dialog box as a list of all the available submissions with a comments area for viewing additional information on the selected submission. However, if this is the first time that you started up the application after installing the software, the list will be blank.

19. Look at the bottom of the *Open Report Data Dialog box*. You will see four option buttons that are described below:

New Report Data	Clicking this button displays the *New Report Data Dialog box*, which allows the creation of a new submission report file. The dialog box displays areas for the report type, as well as areas for entering a descriptive name for the submission, a file name, and comments. Any descriptive name may be assigned to a new submission report file, as long as it is unique to the submission list and not blank. It is a good idea to use a name that distinctly identifies the report. Use alphanumeric characters for file names.

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Open	Clicking this button closes the *Open Report Data Dialog box*, and opens the selected submission. In addition, double-clicking on a submission or pressing the **Enter** key while a submission is highlighted will also open the submission. For complete information on creating or editing a submission, see *Preparing a Submission*, beginning on 42.
Cancel	Clicking this button closes the *Open Report Data Dialog box* with no changes to the screen.
Help	Clicking this button displays the help text for the *Open Report Data Dialog box*.

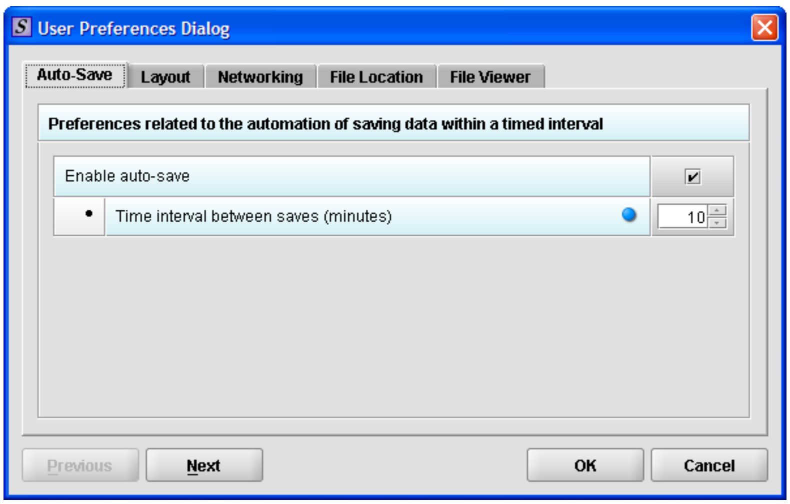
Subsection 2.2: Setting User Preferences

Introduction

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

- Auto Save
- Layout
- 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.

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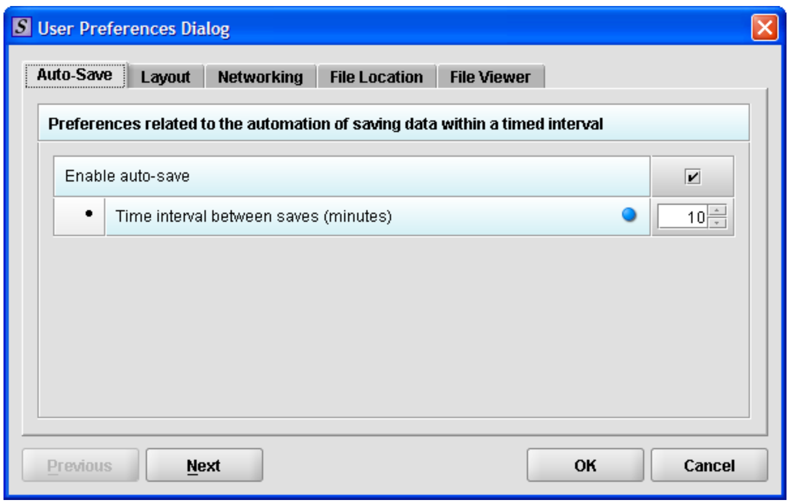
Auto Save

- **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 turned on, and set to save files at 10 minute intervals.

<u>Note:</u> The **Blue Dot**  indicates a required question.



To change the auto-save option:

	Action	Graphic
1.	Check or uncheck the **box** to select the enable auto-save checkbox (to turn auto save on) or click to clear the checkbox (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.	

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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

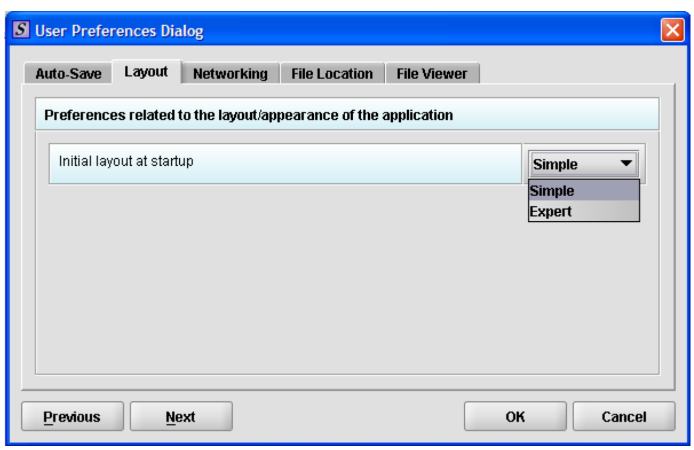
- If you are finished and satisfied with your changes, click **OK** to close the *User Preferences Dialog box*.

OR

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

Layout

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



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

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

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

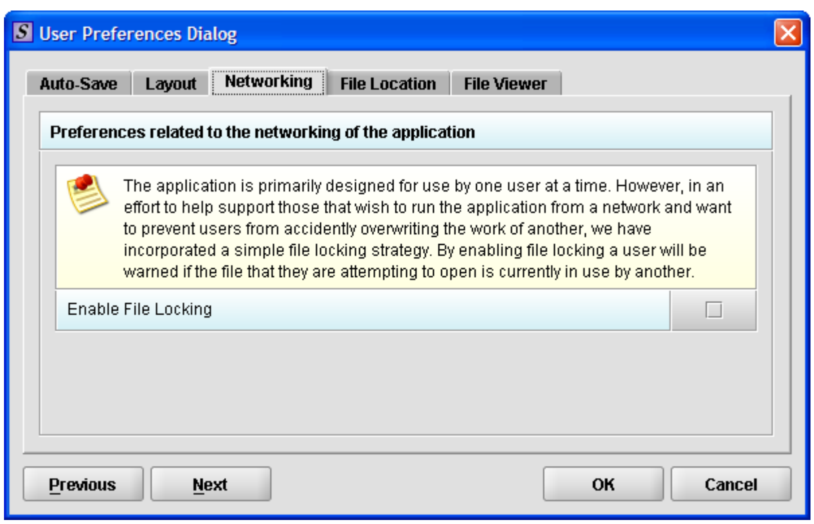
- If you are finished and satisfied with your changes, click **OK** to close the *User Preferences Dialog box*.

OR

- Click **Cancel** to close the *User Preferences Dialog box* without making 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 want 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. At default, eSubmitter opens without file locking.



To enable file locking, follow the instructions below.

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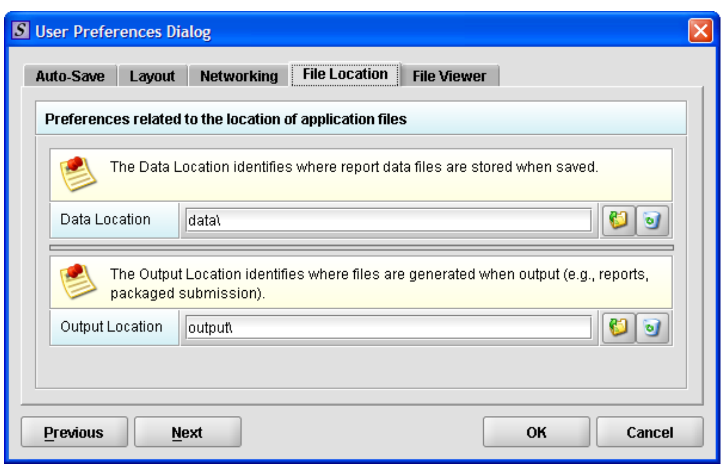
Subsection 2.2: Setting User Preferences

	Action	Graphic
1.	Click to select the **Enable File Locking** checkbox (to turn file locking on) or click to clear the checkbox (to turn file locking off).	
2.	If you are finished and satisfied with your changes, click **OK** to close the *User Preferences Dialog box*. **OR** Click **Cancel** to close the *User Preferences Dialog box* without making any changes.	 

File Location Allows you to change the location where your report data files are stored when saved and the location where files are generated when output (e.g., reports and packaged submissions). For more information on packaging files for submission, go to *Package Files for Submission* on page 83.



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.	

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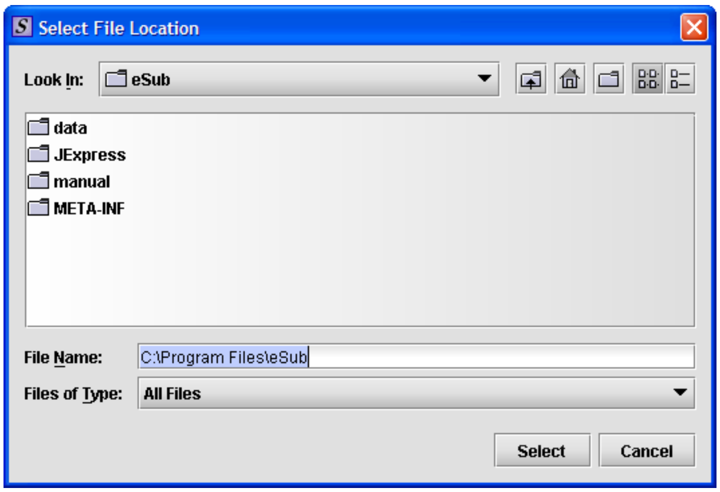
2. The *Select File Location dialog box* will appear. Click the **Look In** box, and navigate to the file folder where you would like your files stored.

Select File Location Box



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

   Recommended Location:

   If installed on a Network drive (on 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.

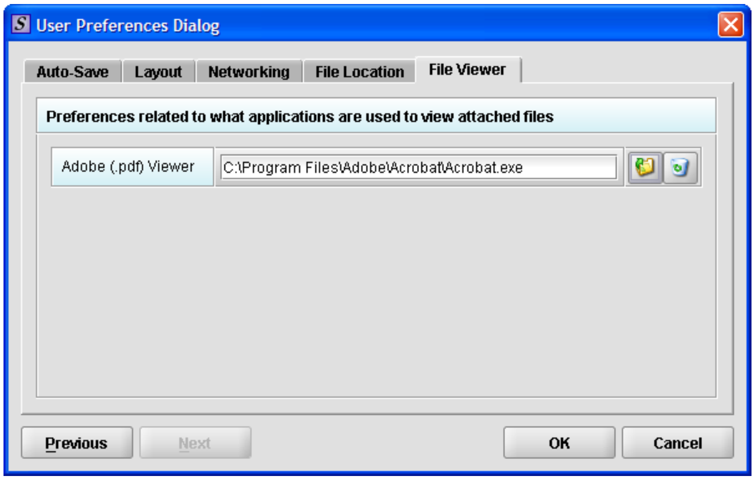
   If installed on a Workstation (on Windows Vista): data and output files should be hosted in the following location: **C:\Users\Public\eSub_Home**.

   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

File Viewer

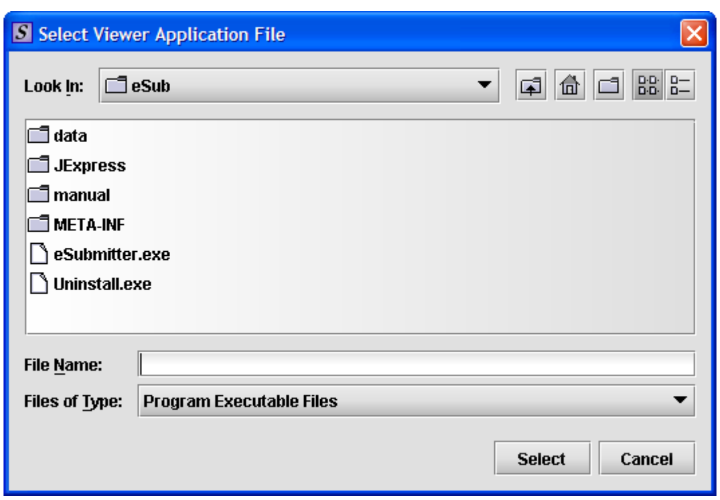
Allows you to identify the application that you will use as your PDF viewer. (Generally, Adobe Acrobat is used as the application for viewing PDFs.)



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).	

Select Viewer Application File Box



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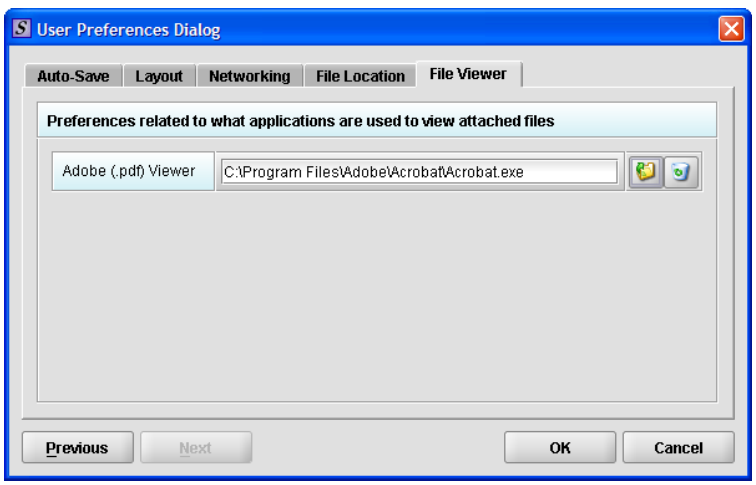
2. Click in the **Look In** box, and navigate to the file folder for Adobe Acrobat or the Acrobat Reader. The location is usually either:

   - **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.

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.

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

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

Create a new Blank Submission Report from Scratch

To create a new submission report from scratch:

	Action	Graphic
1.	The CeSub eSubmitter application should be open on your computer desktop. If it is open, and you see the **General Screen**, go to step 2. (If it is not open, open the application first by following the instructions in *Starting the Software* on page 10.)	
2.	Click **File > New**. (Or, click the **New Report** icon on the Tool Bar.) The *New Report Data Dialog box* is displayed.	

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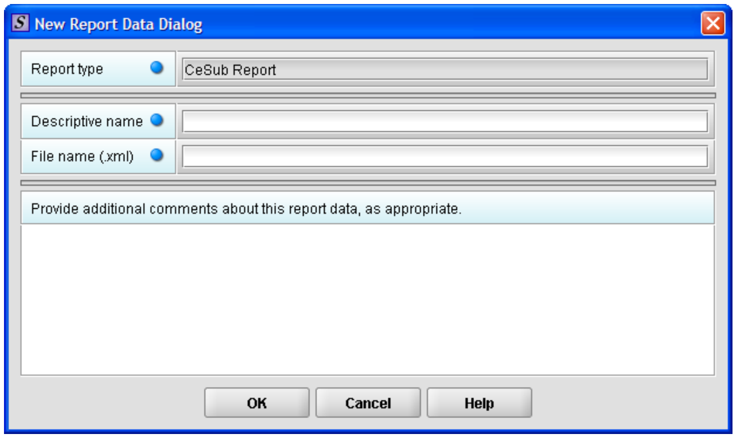
New Report Data Dialog Box



3. Complete the fields on this dialog box as follows:

- **Report type** – The entry is CeSub Report. **Do not change this entry**. (Required Entry, as indicated by the blue dot.)

- **Descriptive name** – Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (Required Entry, as indicated by the blue dot.)

- **File name** – Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.) **File names should not contain more than 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).

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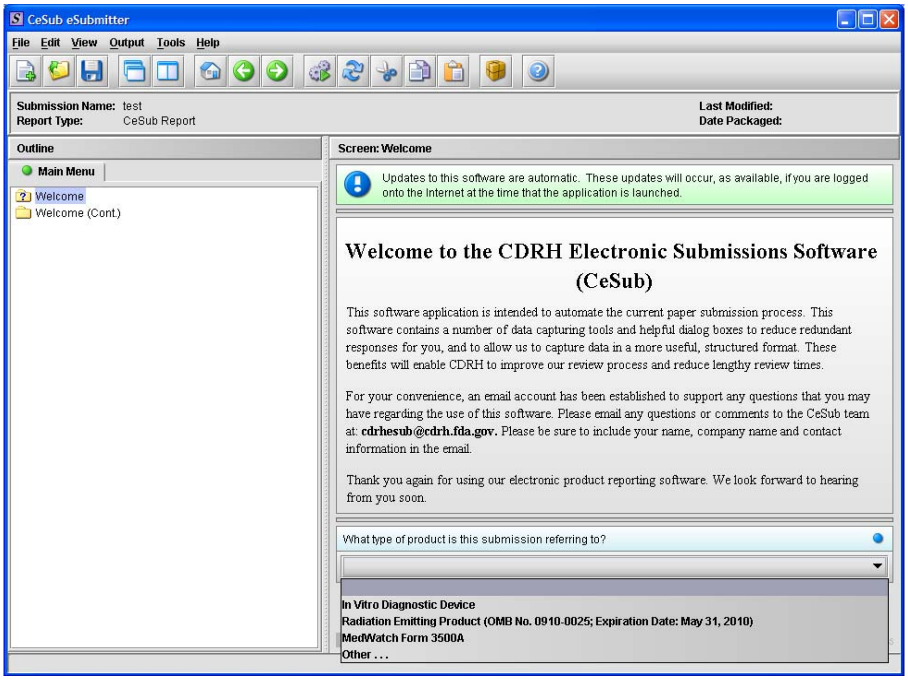
Subsection 2.3: Creating a New Submission

4. When you are finished entering all information in the fields, click **OK**. The first screen of your new blank submission report is displayed.



5. Click the drop-down menu, and select one of the following: **In Vitro Diagnostic Device**, **Radiation Emitting Product**, **MedWatch Form 3500A**, or **Other**.

6. Click the **Welcome (Cont.)** node.

   NOTE: If you are in the simple layout, click the next arrow button.

7. You are now ready to change the responses in this submission, go to *Entering Submission Information* on page 49.

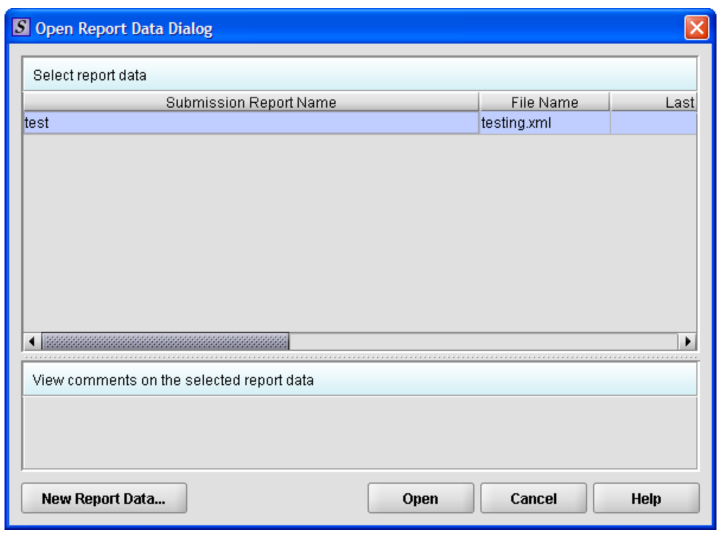
Subsection 2.4: Copy an Existing Submission to Create a New Submission

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

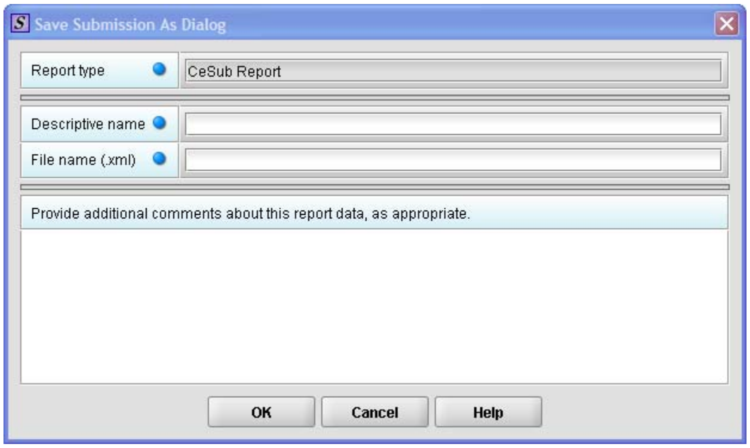


	Action	Graphic
2.	Click to select the existing submission report to be used as a template, and click **Open**. The submission report is displayed on your computer.	
3.	Click **File** > **Save As**. The *Save Submission As Dialog box* is displayed (as shown below).	

Continued on Next Page

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

Save Submission As Dialog Box



4. Complete the fields on this dialog box as follows:

- **Report type –** The entry is CeSub Report. **Do not change this entry.** (Required Entry, as indicated by the blue dot.)

- **Descriptive name** – Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (Required Entry, as indicated by the blue dot.)

- **File name** – Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.)

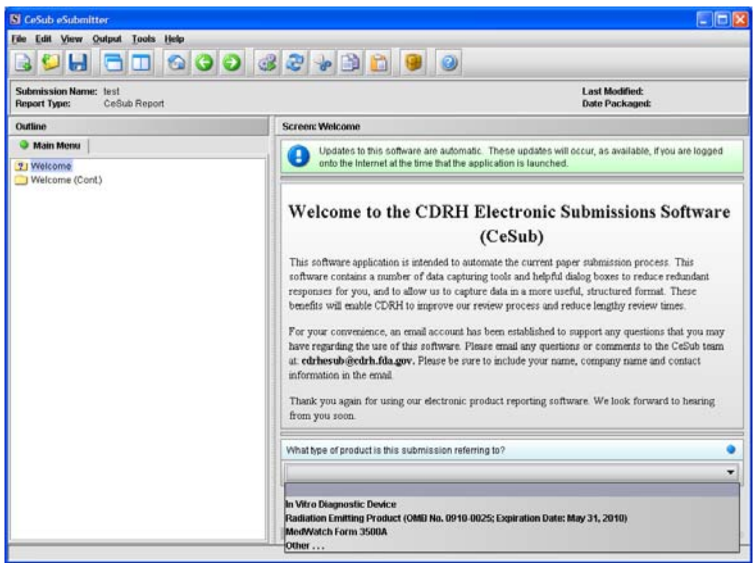
- **Provide additional comments**… – Enter any additional information about this report (Optional Entry).

Continued on Next Page

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

   The first screen of your new submission report is displayed.

Submission Report Main Screen



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.) On this screen:

   - Click the drop-down menu, and select one of the following: **In Vitro Diagnostic Device**, **Radiation Emitting Product**, **MedWatch Form 3500A**, or **Other**.

Continued on Next Page

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

7.	Click the **Welcome (Cont.)** node. NOTE: If you are in the simple layout, click the next arrow.	
8.	You are now ready to change the responses in this submission, go to *Entering Submission Information* on page 49.	

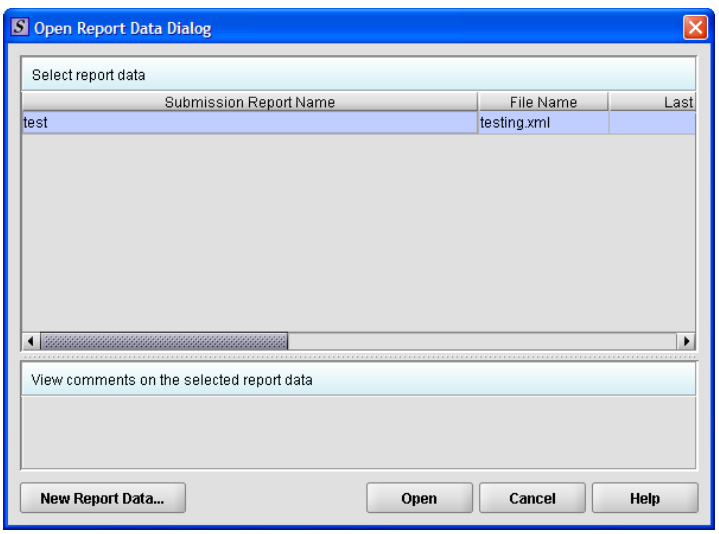
Subsection 2.5: Re-open an Existing Submission

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 Report Data Dialog box* is displayed (as shown below).	

Open Report Data Dialog Box



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

Section 3: Interface

Contents

This section contains the following topics:

Subsection 3.1: Application Window

Introduction

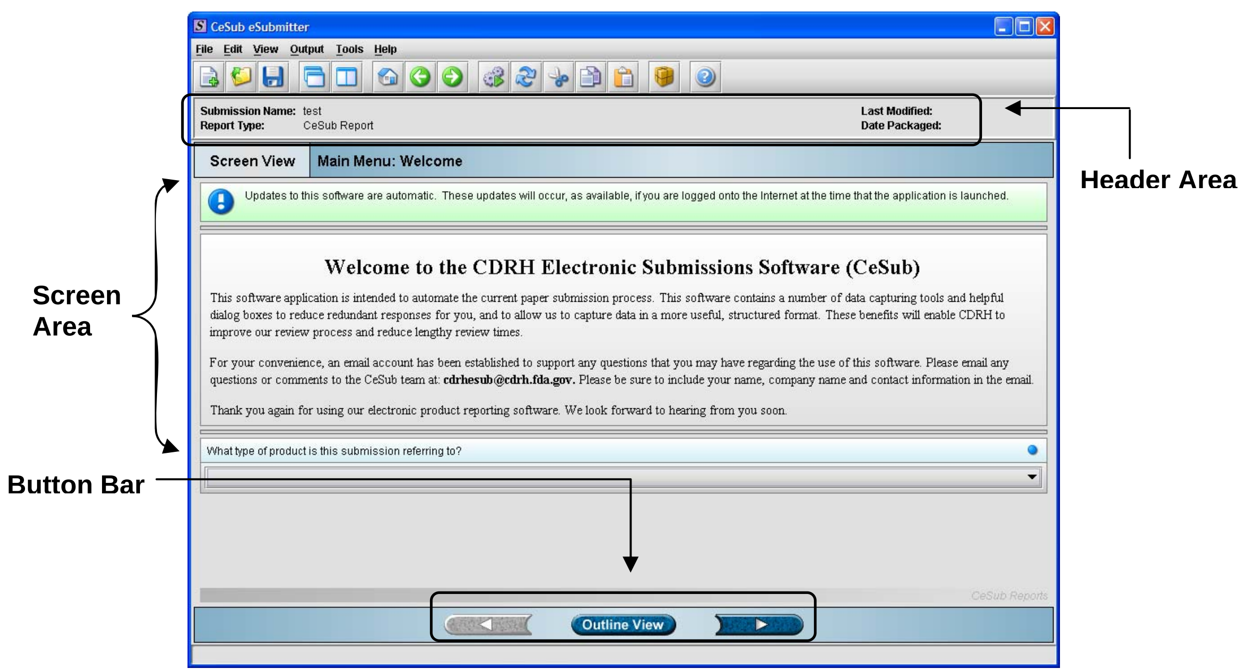
This section describes eSubmitter's Application Window and its different parts.

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

Simple View

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

- **Header Area** (located at the top)
- **Outline Area** or **Screen Area** (located in the middle)
- **Button 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.

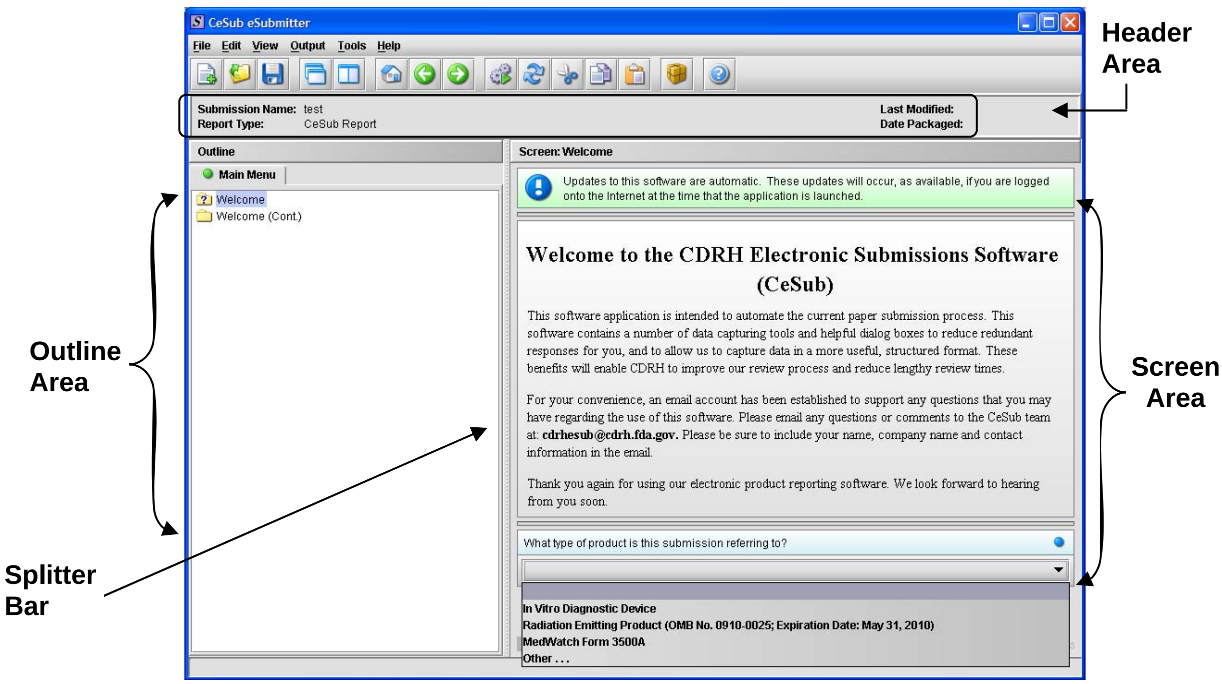


Subsection 3.1: Application Window

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)

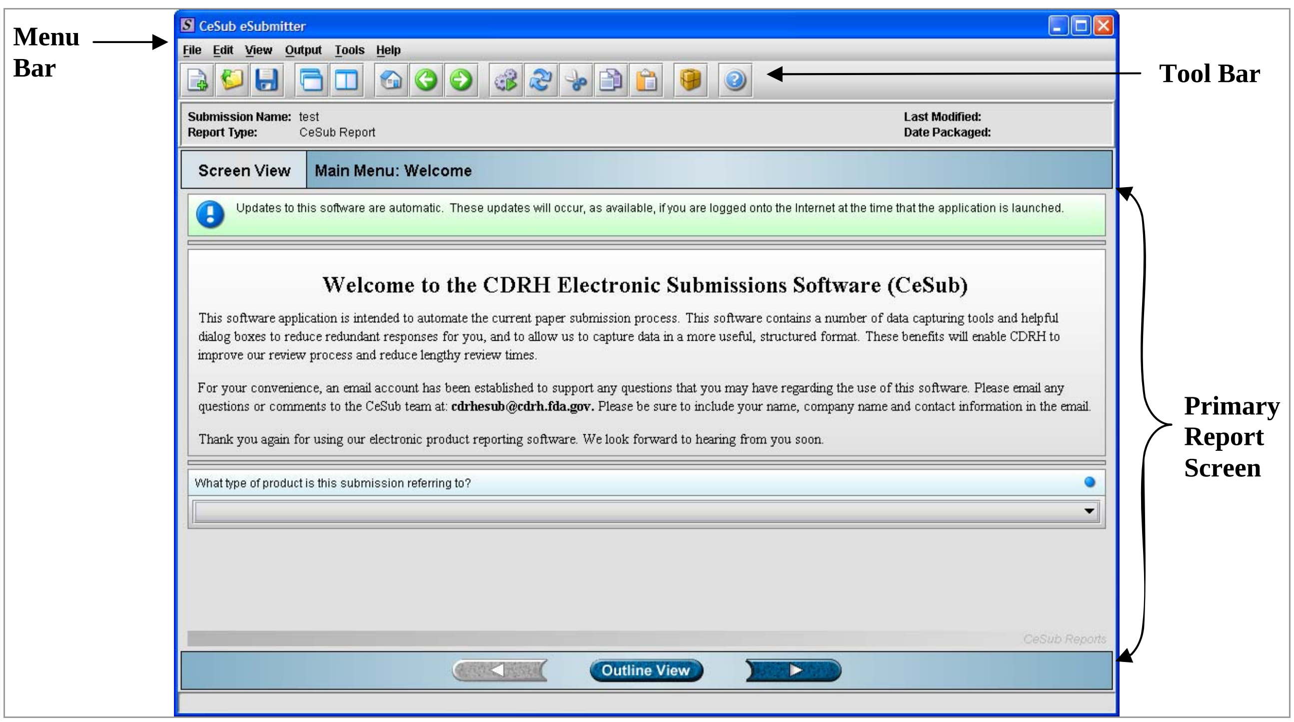


Layouts

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** – is the name that you created for the report.

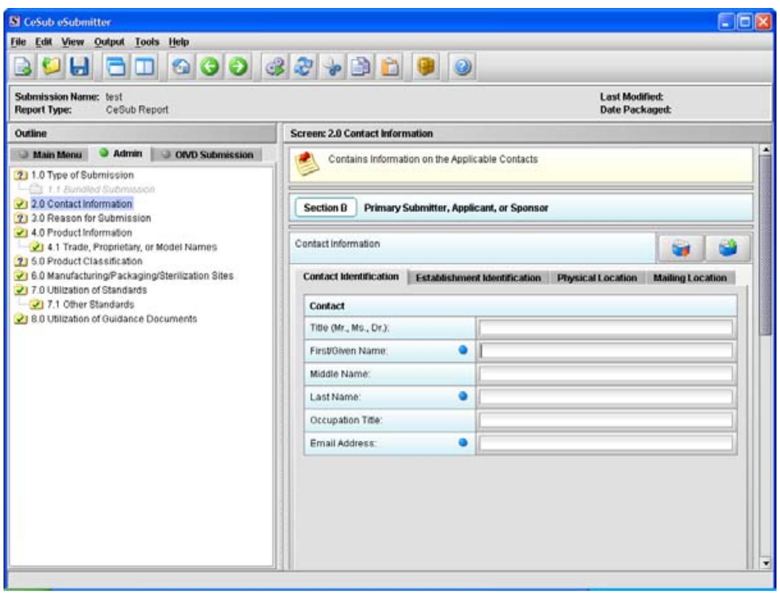
- **Report Type** – will always be CeSub Report.

- **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 CDRH. The date and time are automatically set after the files are packaged for submission to CDRH.

Outline Area/View

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



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

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

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

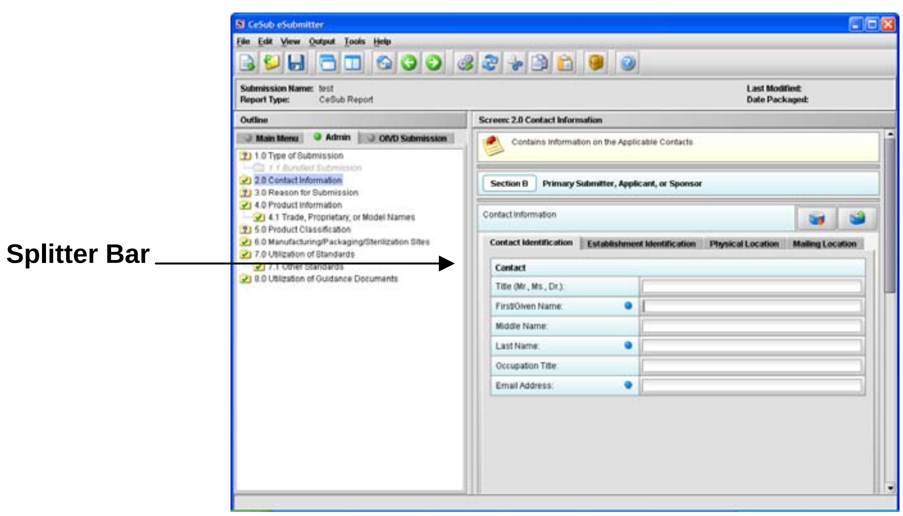
Screen Area/View

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

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



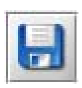
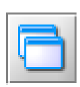
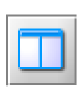
Subsection 3.2: Toolbar

Introduction

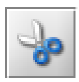
The tool bar is a row of buttons that are designed to provide quick access to specific or commonly used commands and options. The tool bar is located below the menu bar.

> **<u>Note:</u>** The screens and information that are accessed through the icons can also be accessed using the following menus: **File**, **Edit**, **View**, and **Help**. However, you must access information for **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 42 and 94 respectively.

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

Tool	Function
	**New** – Displays the *New Template Dialog box*, which allows a new (empty) template to be created.
	**Open** – Displays the *Open Template Dialog 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.

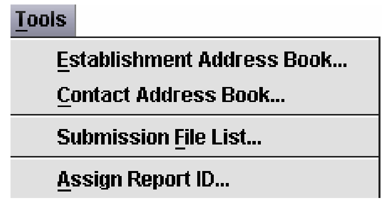
Continued on Next Page

	**Previous –** Allows you to navigate to the previous screen.
	**Next –** Allows you to navigate 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**
	**Cut**
	**Copy**
	**Paste**
	**Package Files for Submission –** Allows you to package your submission to send to CDRH after you have completely answered all questions, and no data is missing. For complete information, see *Packaging Submission Files* on page 83.
	**Help Topics**

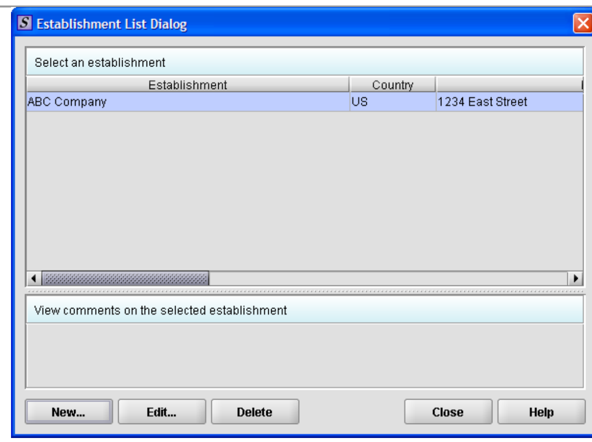
Subsection 3.3: Menu Bar - Tools

Introduction

Each command on the Tools Menu is described below:



<table>
<tr><th>Tool</th><th>Function</th></tr>
<tr><td>Establishment Address Book</td><td>
Displays the Establishment List Dialog box, which provides the ability to maintain the addresses of the pertinent manufacturing and corporate facilities associated with your reports.



You only need to enter each company name and address once into the Establishment 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 Establishment Address Book will always be accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries.

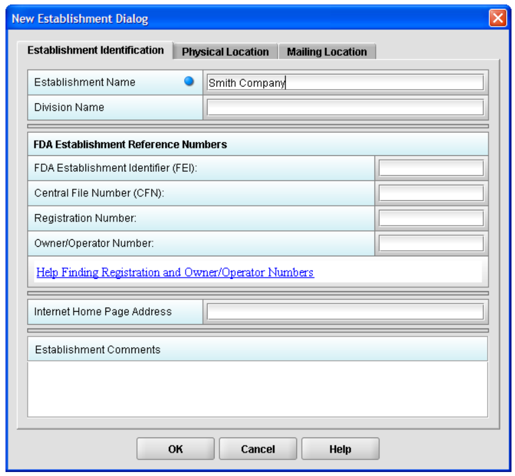
The Establishment List Dialog box contains a list of all the available establishments and a comments area for viewing the comments on the selected establishment. In addition, if you scroll across the establishment list, you’ll see fields containing basic identifier information about each establishment.

The options (New, Edit, Delete, Close, and, Help) in this dialog box are described below:
</td></tr>
</table>

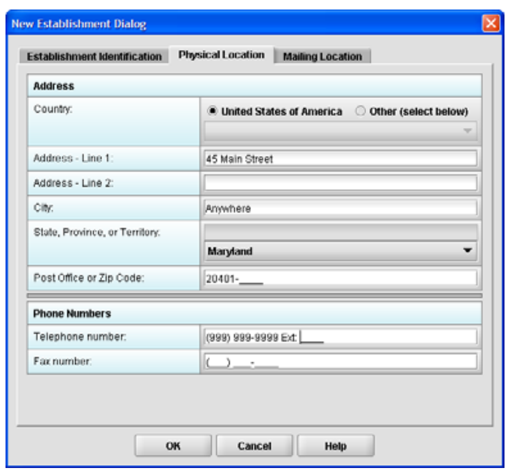
Continued on Next Page

New

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

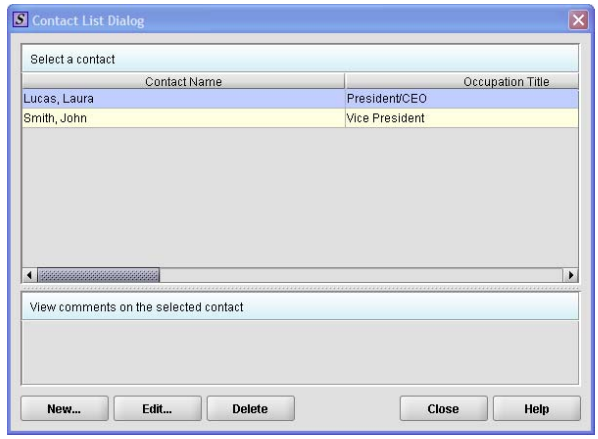


⇒ Click the **Physical Location** tab to enter address information for where the establishment is physically located. See below.



⇒ Click the **Mailing Location** tab to enter address information for the mailing address of the establishment. See below.

	 ⇒ Click **Copy Address** if the mailing location is the same as the physical location of the establishment. The information is automatically copied into the address fields (as shown above). However, if the mailing location differs drastically from the physical location, you must manually enter the information. ⇒ When you are finished with the addresses, click **OK** to save your edits. Click **Cancel** to ignore all edits or **Help** to see help text. You return to the Establishment List Dialog box.
Edit	Displays the *Edit Establishment Dialog box*, which allows the selected establishment information to be changed. (You enter information in this dialog box in the same manner as the *New Establishment Dialog box*.)
Delete	Deletes the selected establishment from the list.
Close	Closes the dialog box.
Help	Displays the help window with text.

<table>
<tr><th>Tool</th><th>Function</th></tr>
<tr><td>Contact Address Book</td><td>


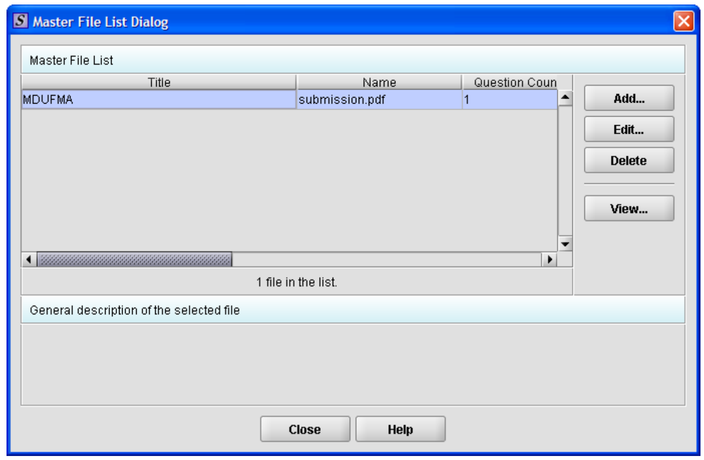
Displays the Contact List Dialog box, which allows the names and addresses of the pertinent people associated with the report to be maintained. You only need to enter each person's name and contact information once into the Contacts Address Book, and then you can select the appropriate individual in response to each question. Existing Establishment addresses can be selected (from the Establishment Address Book) for each contact. The Contact Address Book will be retained and accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries.

The Contact List Dialog box contains a list of all the available contacts and a comments area for viewing the comments on the selected contact. In addition, if you scroll across the contact list, you will see fields containing basic identifier information about each contact.

The options provided in this dialog box are described below:
</td></tr>
</table>

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

Subsection 3.3: Menu Bar - Tools

<table>
<tr><th>Tool</th><th>Function</th></tr>
<tr><td>Submission File List</td><td>


Displays the Master File List Dialog box, which allows attached file information to be entered once for a submission but reused across questions in the report. For complete information on preparing a submission, see page 48. File attachments must be in PDF.

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 24.

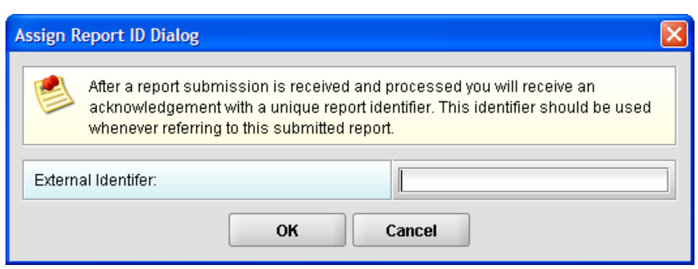
<u>Note:</u> The file list is specific to the report that is currently open.

The Master File List Dialog box manages the file attachment information related to the open report. The dialog box contains a list of all the attached files that are currently available, an area for general information on the selected file, and options for managing the list. The file list displays the following for each:

Descriptive title
Physical file name
Number of questions that currently reference the file as an attachment
File date
File size
Path to the file location

The options provided in the dialog box are described below:
</td></tr>
</table>

Add	Displays the *New File Dialog box*, which allows a new file to be added to the list of attachments.
Edit	Displays the *Edit File Dialog box*, which allows the selected file title and general description to be changed.
Delete	Deletes the selected file from the list.
View	Displays the selected file within the specified PDF viewer.
Close	Closes the dialog box.
Help	Displays the help window with text.

Tool	Function
Assign Report ID	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 an acknowledgement, you can record the unique identifier assigned by CDRH (such as an accession number). For complete information on preparing a submission, see page 48. **To enter a Report ID:** ⇒ Select **Assign Report ID** from Tools on the Menu bar. You see the *Assign Report ID dialog box*, as shown below. ⇒ Enter the unique identifier assigned by CDRH. ⇒ 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:

Subsection 4.1: Entering Submission Information

Introduction

Entering information for a submission requires stepping through the report and answering questions. If you use the simple layout, you progress through the report screen by screen, ensuring that you have filled in all appropriate responses. If you use the expert layout, you progress through the report outline sections, activate each section to load the section questions and responses, and ensure that you have filled in all appropriate responses.

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

For additional information on the simple and expert layouts, see *Interface* on page 34. 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 report.

Question Types

The CeSub eSubmitter application 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.

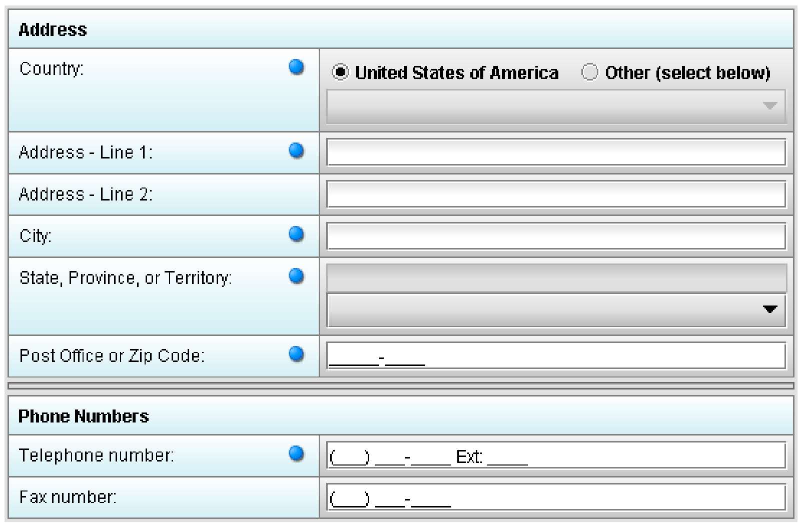
This section describes each of the different question types and includes examples of their respective responses.

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: Entering Submission Information

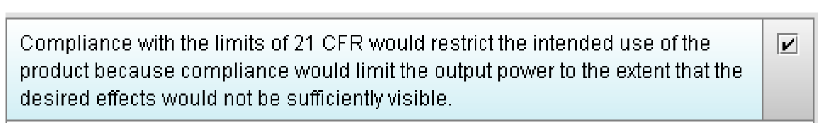
Address

This question type requires that you enter the address and phone numbers of your establishment. You enter the information in text boxes and make selections using drop-down menus and clicking option buttons. An example is shown below. Other types of address questions are **Contact** and **Establishment**, which will be discussed below.



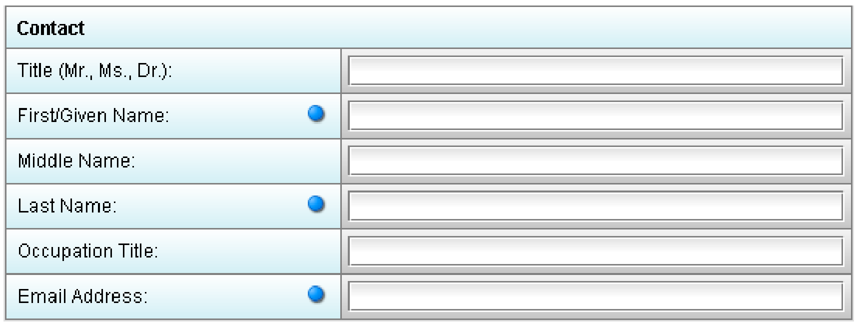
Check Box

This question type requires that you click on the box to select or clear the check mark to answer a question. See the example below.



Continued on Next Page

<table>
<tr>
<td>Contact (Simple)</td>
<td>This question type requires that you type contact information (first name, last name, etc.) in text boxes. Entries may or may not be required. The figure below shows an example of a simple contact question with the first name and last name as required entries (as indicated by the blue dots).

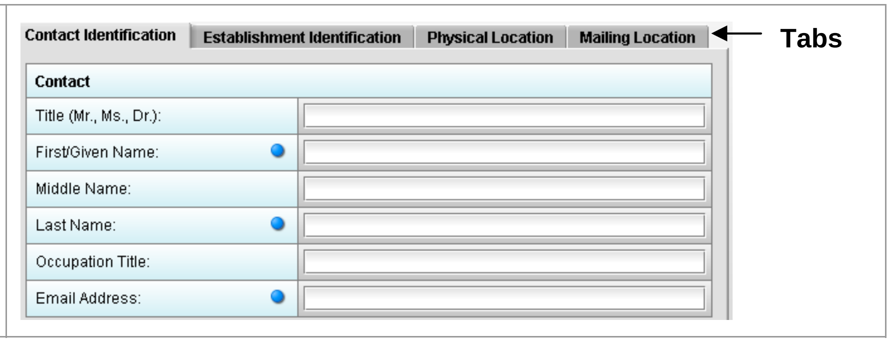


Entries in a simple contact question are saved with a specific submission but will not be captured in the Establishment or Contact Address Book. For more information about Establishment Address Books, see page 42.</td>
</tr>
</table>

<table>
<tr>
<td>Contact (Multi-Part)</td>
<td>This question types contains various areas that you need to complete (indicated by the tabs: Establishment Identification, Physical Location, and Mailing Location). For this question type, you may enter contact information (first name, last name, etc.) directly into text boxes, or you may copy this information from the Contact Address Book. When you enter the information directly (without using the Contact Address Book), the contact information is only saved for the submission. Copying the information from the Contact Address Book saves time for data entry because the information is automatically copied into the question. Information in the Establishment and Contact Address Books requires that you only enter the data once and reuse it across multiple submissions.

The figure below shows an example of a multi-part contact question.</td>
</tr>
</table>

Subsection 4.1: Entering Submission Information

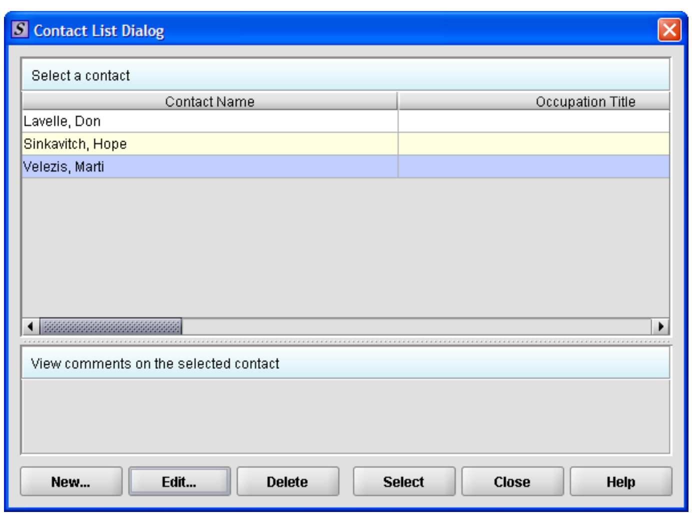


Copy Information from Contact Address Book into Contact Question

To copy information from the Contact Address Book into the Contact Question, 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.	

Contact List Dialog Box

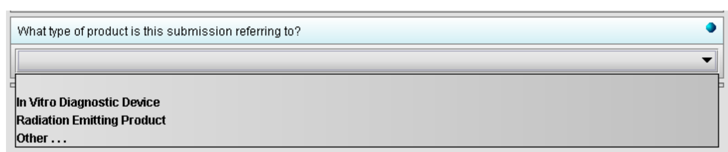


2.	Click to highlight and select the desired contact.

Continued on Next Page

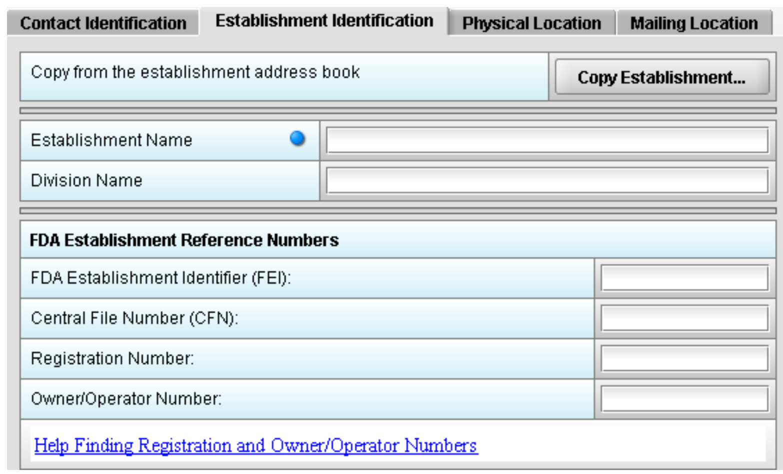
3. Click **Select**. The contact information is automatically populated in the different entry areas.

4. If the information is not exactly the same, you can edit the information after you have copied it.
5. To see the other information, click the desired tab. If you copied the contact information from the Contact Address Book, the information for these tabs will be completed as well.
6. For more information about Contact Address Books, see page 45.

Drop-Down Menu	This question type requires that you select a response from a list of entries that appear after you click the box with the down arrow (). Below is an example of a question with a drop-down menu. 

Establish-ment	This question type contains various areas that you need to complete (indicated by the tabs: Physical Location and Mailing Location). For this question type, you may enter contact information (establishment name, etc.) directly into text boxes, or you may copy this information from the Establishment Address Book. When you enter the information directly (without using the Establishment Address Book), the establishment information is only saved for the submission. Copying the information from the Address Book saves time for data entry because the information is automatically copied into the question. Information in the Establishment and Contact Address Books requires that you only enter the data once and reuse it across multiple submissions. Below is an example of an establishment question.

Subsection 4.1: Entering Submission Information



Copy Information from Establishment Address Book into Establishment Question

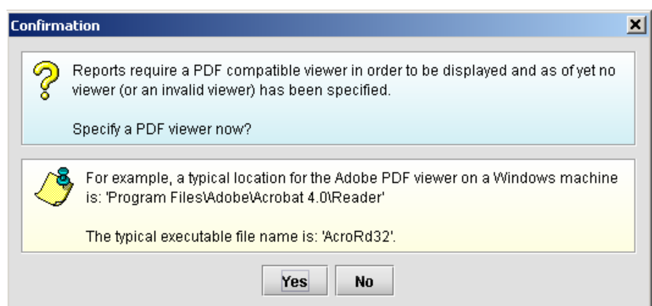
To copy information from the Establishment Address Book into the establishment question, follow the instructions below.

	Action	Graphic
1.	Click the **Copy Establishment** icon in the question.	
2.	Click to highlight and select the desired contact.	
3.	Click **Select**. The contact information is automatically populated in the different entry areas.	
4.	If the information is not exactly the same, you can edit the information after you have copied it.	
5.	To see the other information, click the desired tab. If you copied the contact information from the Contact Address Book, the information for these tabs will be completed as well.	
6.	For more information about Establishment Address Books, see page 42.	

File Attachment

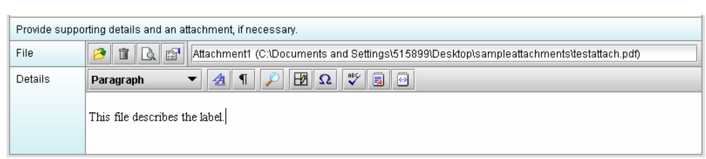
This question type allows you to attach a PDF file as a response. The question may contain a text editor that allows or requires you to type additional information. In addition, this editor may be an HTML Editor, which allows you to format what you type (bold, underline), run spell check, or insert a 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 the descriptive text.

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



Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 24.

Below is an example of an attachment question with a response entered.



<u>Note:</u> You may only attach files that are PDFs; no other formats (such as Microsoft Word or Excel) are acceptable. **File names should not contain more than 250 characters. Do not use symbols when naming the files for attachments**. For example, do **not** use slashes (/) (\), tildes (~), asterisks (*), periods

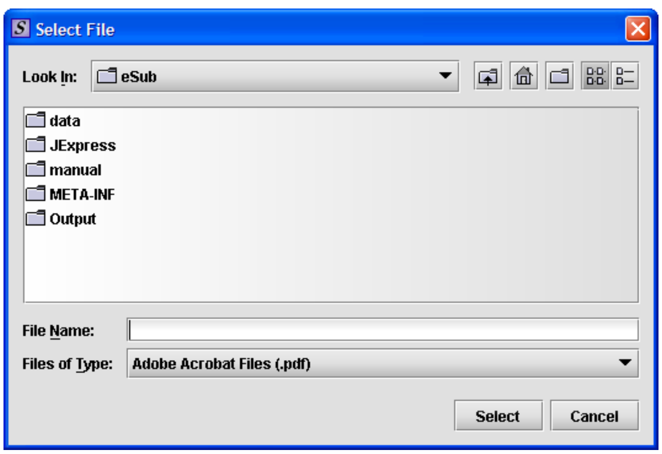
	(.), brackets [ ], single quotation marks (‘), double quotation marks (“) or parentheses ( ). Once the file is attached to a question, it can be selected as an attachment to other questions, if appropriate.

Attach PDF File to Attachment Question

To attach a PDF file to an attachment question, follow the instructions below.

	Action	Graphic
1.	Click the **file folder** icon to select the desired PDF file. A *Select File dialog box* is displayed (as shown below).	

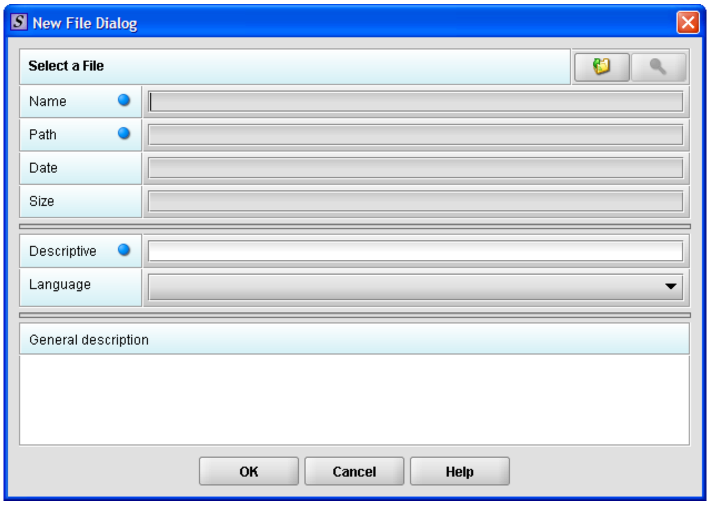
Select File Dialog Box



2.	Click to select the desired file (if it is listed). **OR** Click the **Add** icon to place another file in the list. A *New File Dialog box* is displayed.	

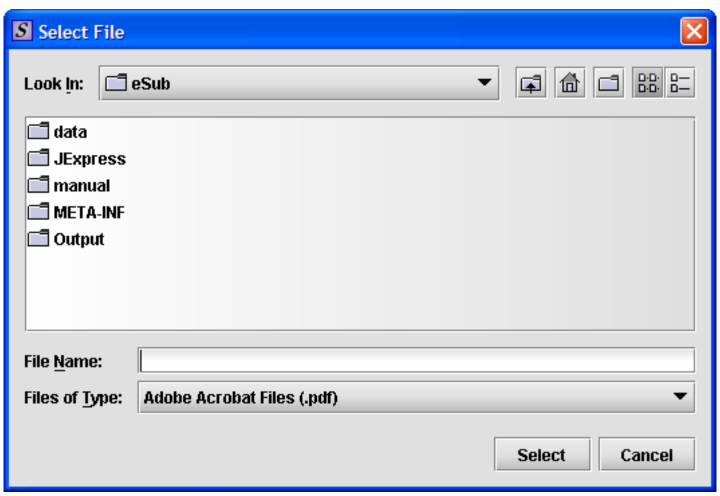
Continued on Next Page

New File Dialog Box



3. Click the **file folder** icon. You will see a *Select File Dialog box.*

Select File Dialog Box



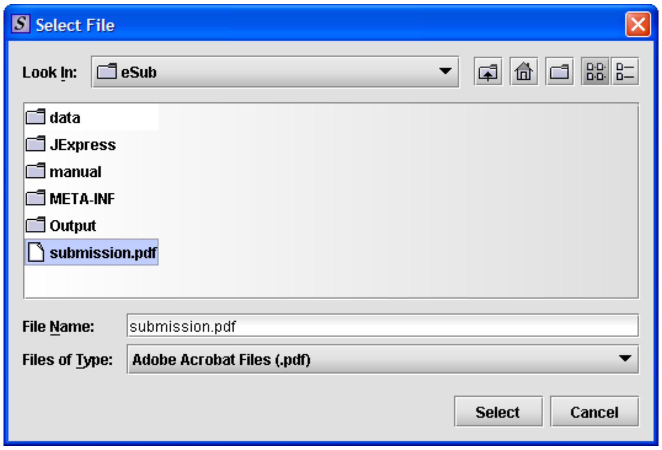
4. Click in **Look In** to locate the drive, such as Local Disk (C:), or folder where the PDF is stored.

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

Continued on Next Page

Subsection 4.1: Entering Submission Information

Select File Dialog Box

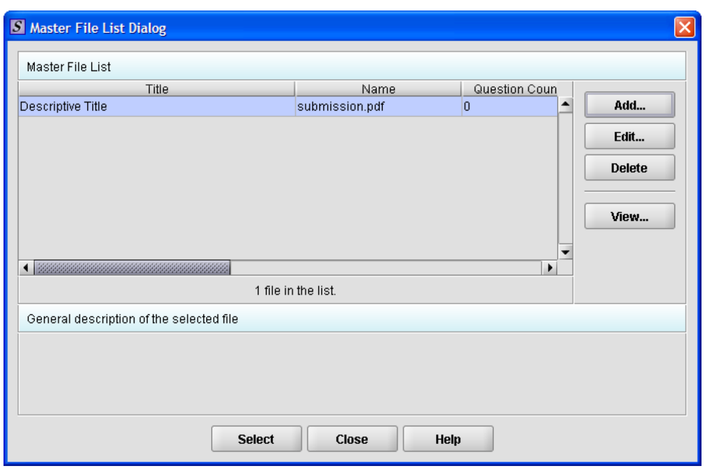


6. Click **Select**. The *Select File dialog box* closes, and you return to *New File Dialog box*.

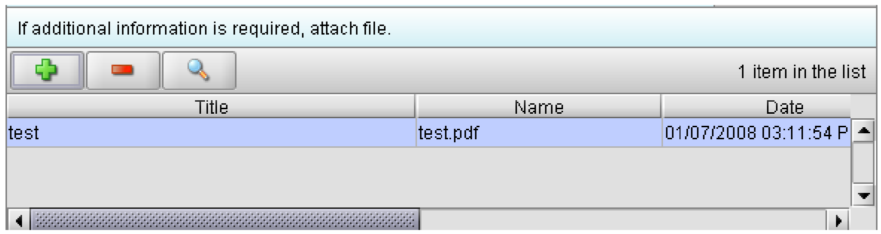
7. Enter a title in **Descriptive title** (required entry) and a description in **General description**, if desired.

8. Click **OK**. You return to the *Master File List Dialog box*. The PDF that you just added is automatically selected (highlighted).

Master File List Dialog Box



9. Click **Select**. You see the path (location) of the file on the network drive or hard drive of your computer appear in the file attachment question.

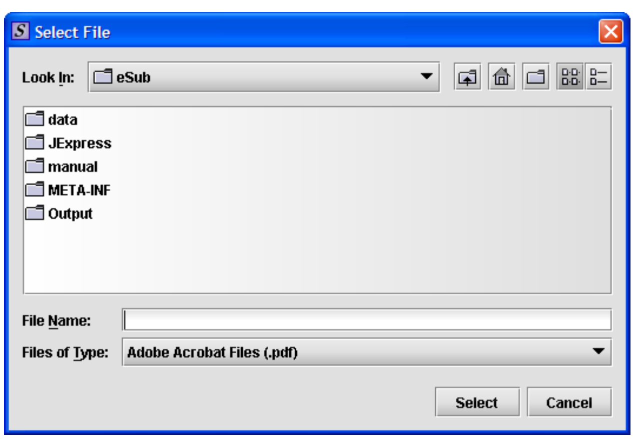
Multiple File Attachments	This question type allows you to attach multiple PDF files as a response. Below is an example of an attachment question with a file attachment included. 

Attach Multiple PDF Files to Attachment Question

To attach multiple PDF files to an attachment question, follow the instructions below.

	Action	Graphic
1.	Click the **Add File** icon. You see a *Select File Dialog box*.	

Select File Dialog Box



	Action	Graphic
2.	Click to select the desired file (if it is listed). **OR** Click **Add** to place another file in the list.	

Continued on Next Page

3. Click **Select**. You see information about the file appear.

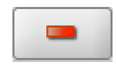
4. To see additional information, use the scroll bar.

5. Click the **Add File** icon and repeat steps 2 and 3 to add another file attachment.

6. Repeat step 5 for each file that you wish to add.

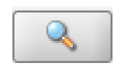
OR

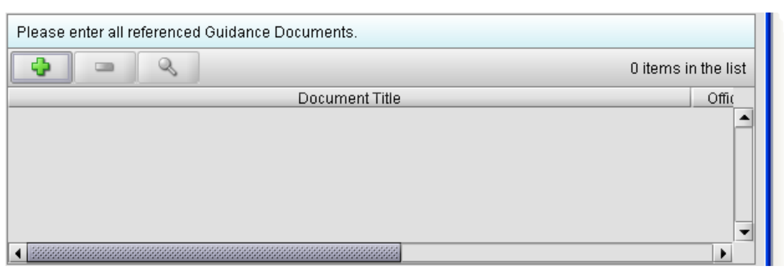
Click the **Delete File** icon to remove a file from the attachment question.



OR

Click the **View File** icon to see a PDF file in the list of files.



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

Select a Guidance Document

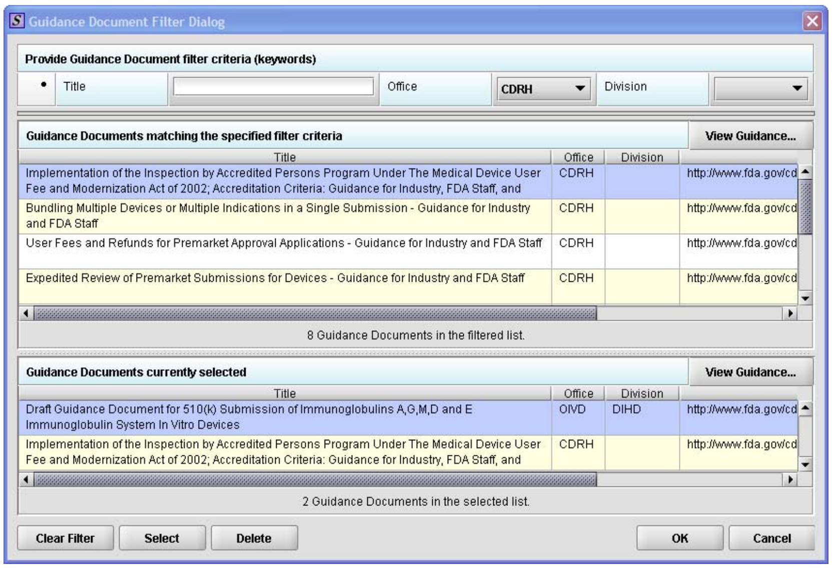
To select a guidance document, follow the instructions below.

Continued on Next Page

Subsection 4.1: Entering Submission Information

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

Guidance Document Filter Dialog Box



Action	Graphic
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.	

Continued on Next Page

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

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

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

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

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

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

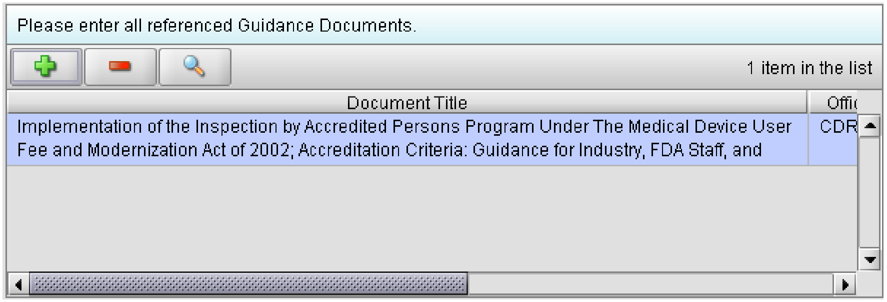
7. Click **OK** when you have made your selections.

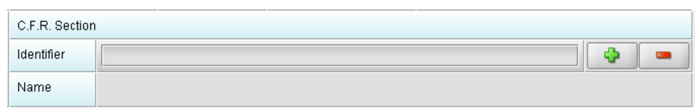
   You return to the guidance document question with your selection appearing. Below is an example of a guidance document question containing a response.

Continued on Next Page

Subsection 4.1: Entering Submission Information

Guidance Document Containing a Response



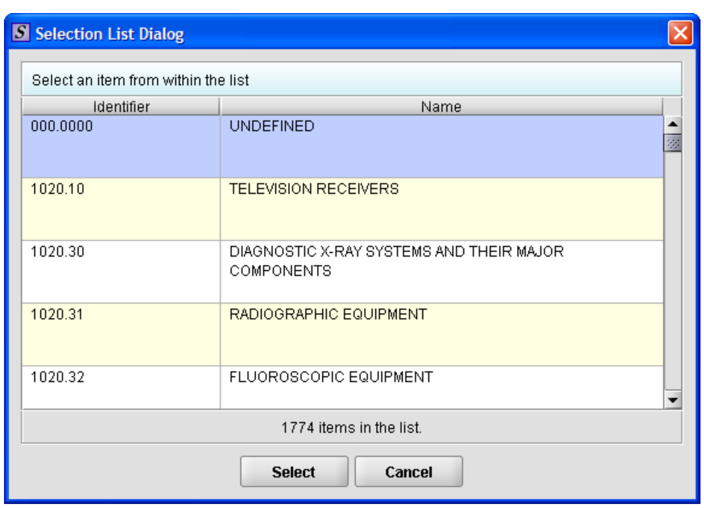
List Item	This question type allows you to select an item from a list of options. Below is an example of a list item question. 

Access the List of Available Options

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

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

Selection List Dialog Box

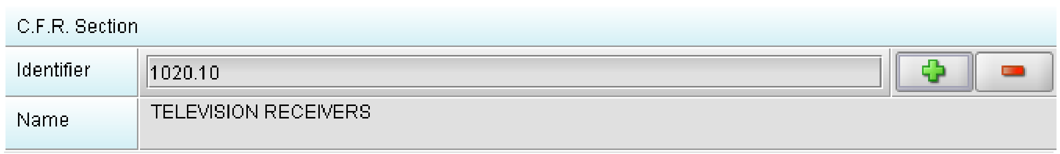


Subsection 4.1: Entering Submission Information

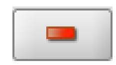
Continued on Next Page

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

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



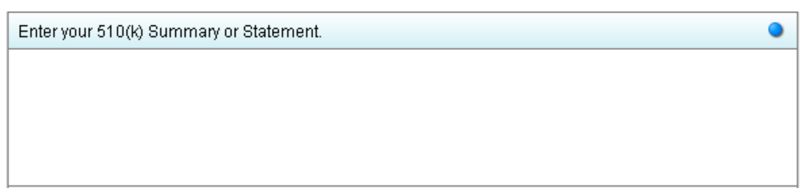
4. If you wish to change your response, click the **delete** icon. Your response selection is deleted from the question.



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

Memo (Multi Line Text)

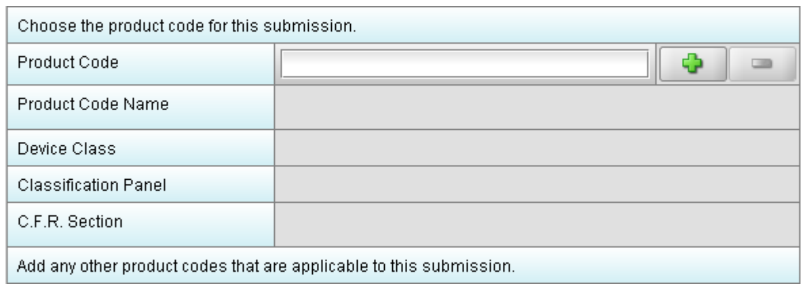
This question type provides an area for you to enter several lines of text (as shown below).



The question may contain a Rich Text Editor which allows you to format what you type (bold, underline), run spell check, or insert a table. The tool bar for the Rich Text Editor will appear after you click in the text area to begin typing. Below is an example of a multi-line question with a rich text editor.

Subsection 4.1: Entering Submission Information

Message	This question type provides information to you as you complete a submission. You may see several different types of messages as you progress through your submission. Different examples of the message types are listed below: • **Information Message** Select the CDRH Recognized Standard from the available list. • **Error Message** Unfortunately, this software currently only supports submissions for in vitro diagnostic devices, radiation emitting products, and medical device adverse event reporting. For all other submissions, please check back at a later date for information on additional submissions that will be supported by this software.Please email any questions or comments to the CeSub team at: cdrhesub@cdrh.fda.gov. Be sure to include your name, company name and contact information in the email.Thank you again for using our electronic product reporting software. • **Note Message** Contains Information on the Applicable Contacts • **Confirmation Message** Save the following changes before closing the report template? • **Warning Message** Any changes made will be lost if they are not saved. Selecting the Cancel button will prevent the operation from continuing (i.e., closing the report template).

Product Code (Single)	This question type allows you to search for and then identify the product code that is assigned to your product or device. If applicable, you are able to search for the device class, device panel and particular CFR section. The response to this question is for a single product code. Below is an example of a product code question. 

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

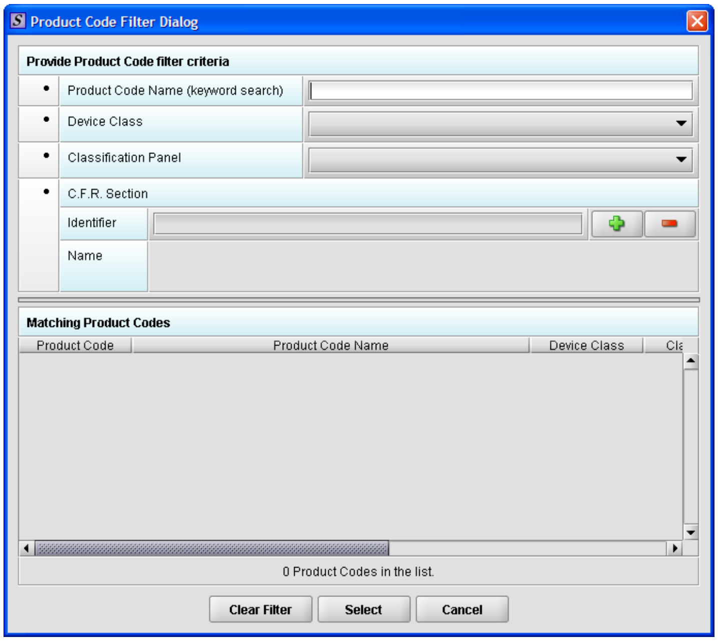
Search for a Three-Letter Code by Keyword

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

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

Continued on Next Page

Product Code Filter Dialog Box



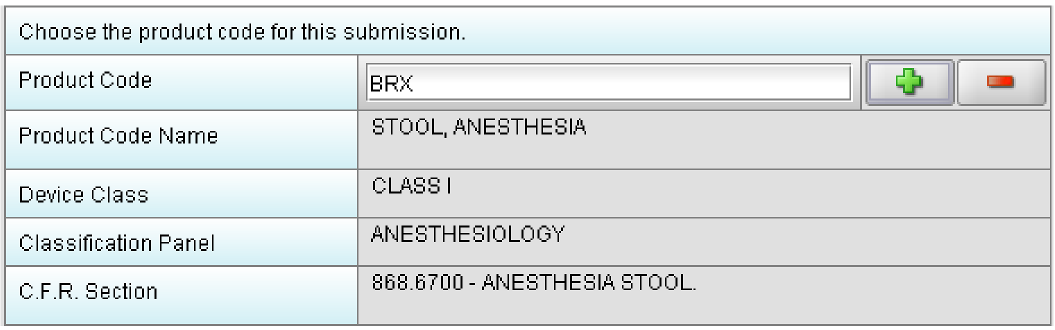
2. Enter a keyword to search the database. You will be provided a list of product codes from which to choose in the **Matching Product Codes** portion of the dialog box.

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 Clear Filter to remove entries and start the search over again.

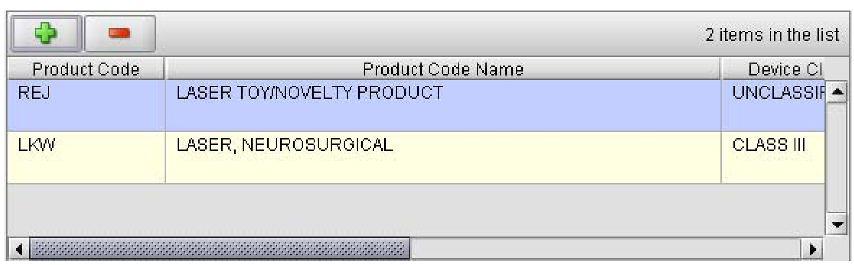
Continued on Next Page

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



Product Codes (Multiple)

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



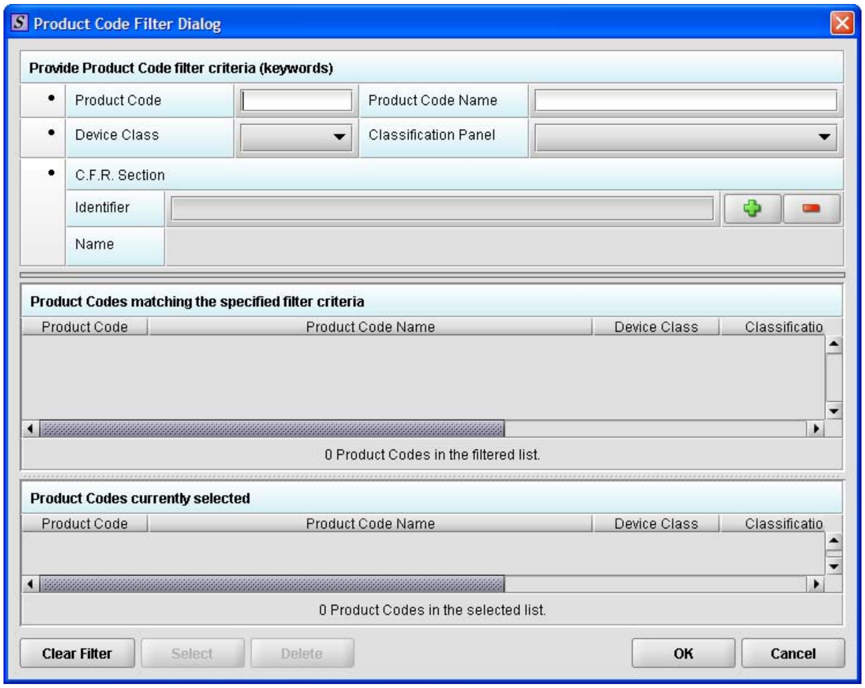
Add Product Codes

To add product codes, follow the instructions below:

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

Continued on Next Page

Product Code Filter Dialog Box



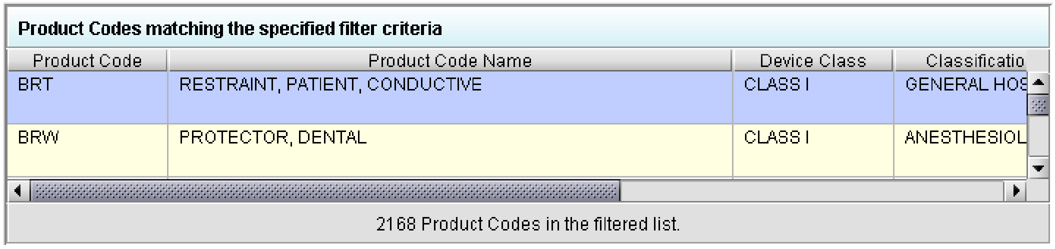
2.	Enter **Product Code** and **Product Code Name** in the appropriate sections.	
3.	Click **OK**.	

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

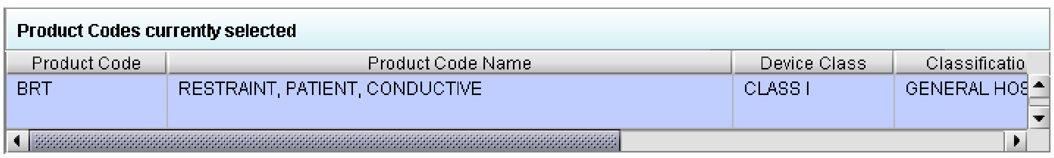


Product Codes matching the specified filter criteria

Product Code	Product Code Name	Device Class	Classificatio
BRT	RESTRAINT, PATIENT, CONDUCTIVE	CLASS I	GENERAL HOS
BRW	PROTECTOR, DENTAL	CLASS I	ANESTHESIOL

2168 Product Codes in the filtered list.

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



Product Codes currently selected

Product Code	Product Code Name	Device Class	Classificatio
BRT	RESTRAINT, PATIENT, CONDUCTIVE	CLASS I	GENERAL HOS

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

   OR

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

   OR

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

Search for Multiple Three-Letter Codes by Keyword

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

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

Continued on Next Page

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.

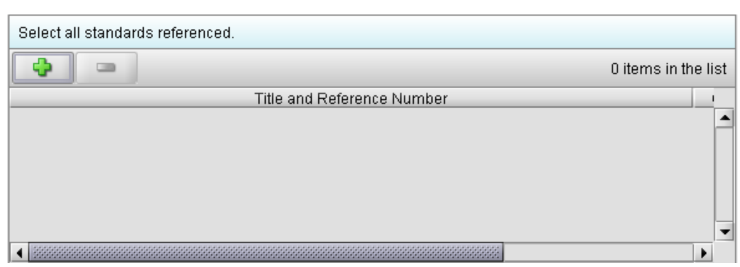
3. Click to highlight the best match to your product/device, and click **Select**. The product/device appears in **Product Codes currently selected**.

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.

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

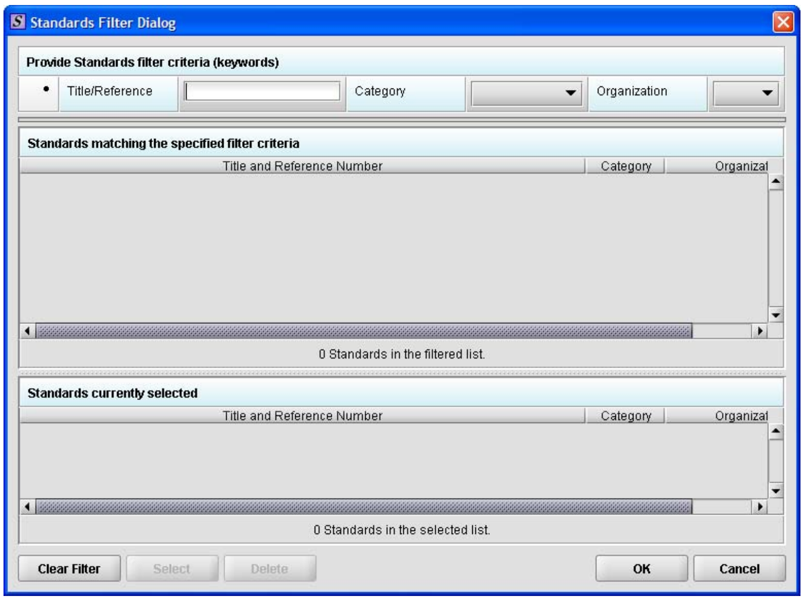
Continued on Next Page

Subsection 4.1: Entering Submission Information

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

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

Standard Filter Dialog Box

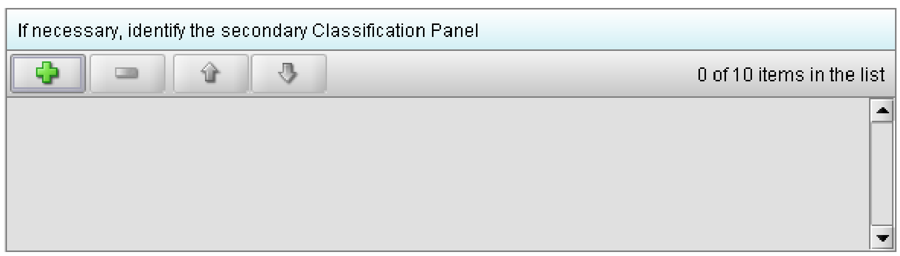


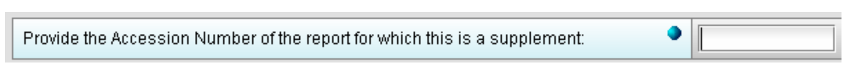
	Action
2.	Enter a title in **Title Reference** (if known) to search the database.
3.	To further refine your search, if desired:

- Click the **Category** drop-down list and make a selection.
- Click the **Organization** drop-down list and make a selection.
- Click  to remove entries and start the search over again.

Continued on Next Page

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.	

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

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

Subsection 4.1: Entering Submission Information

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).

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

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

Subsection 4.1: Entering Submission Information

Entering Responses into the Submission

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

	Action	Graphic
1.	The CeSub 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 10.	
2.	Navigate through the submission as follows: • If you are in the simple layout, use the buttons on the button bar to advance to next/return to previous screen. • If you are in the expert layout, use the outline section, and activate each section to load the questions.	
3.	Provide a response to the question(s) on the screen. The response required depends on the type of question.	
4.	Save your responses periodically.	

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.

<u>Note:</u> 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  on the tool bar. If you do not finish entering information into a submission in one session, you may return to it at another time. See *Reopening an Existing Submission* on page 33.	
2.	If you wish to close the submission, click **File > Close**. The General Screen is 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.

Missing Data

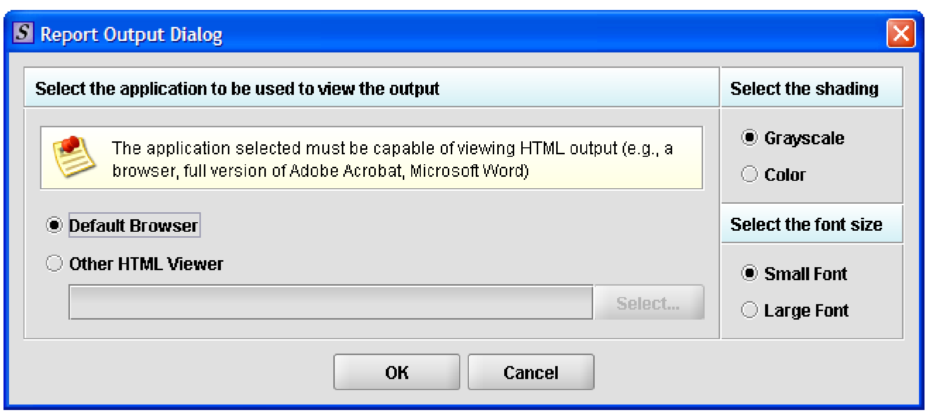
You will only be able to package files for submission as long as no required data is missing from the submission. To determine if any data is missing, you will generate a Missing Data Report. To proceed, the desired submission should be open and displayed on your computer screen.

<u>Note:</u> 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

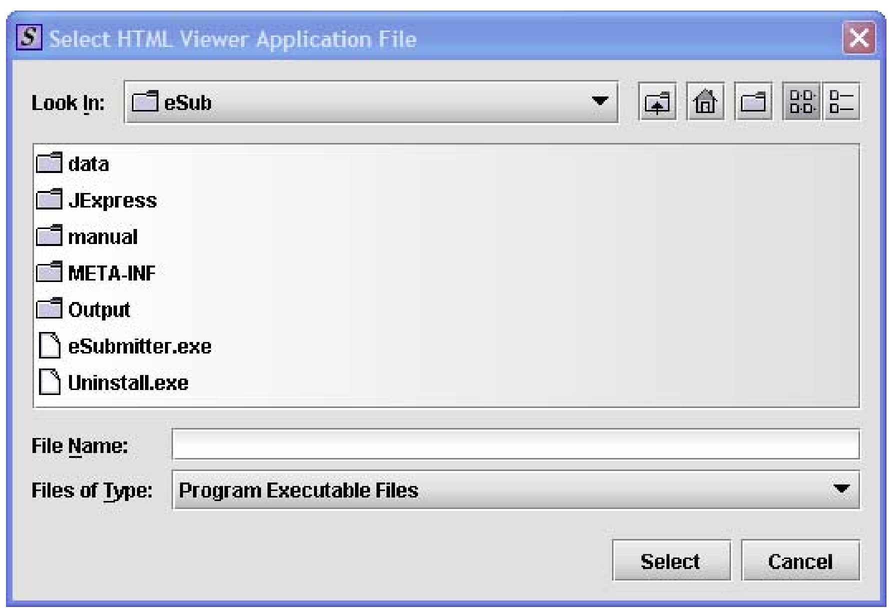
2. On this dialog box:

   - 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

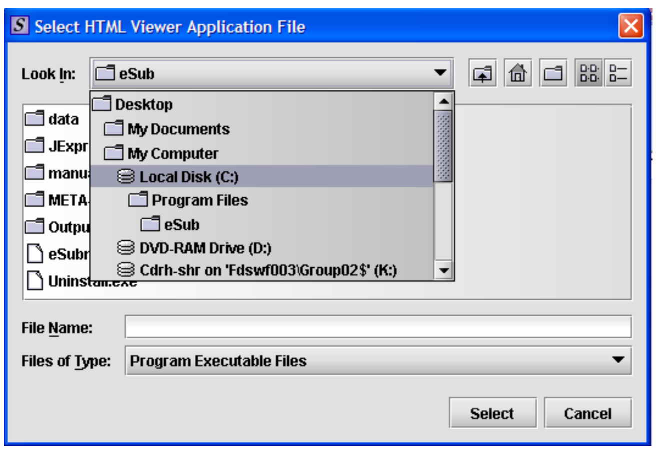


Continued on Next Page

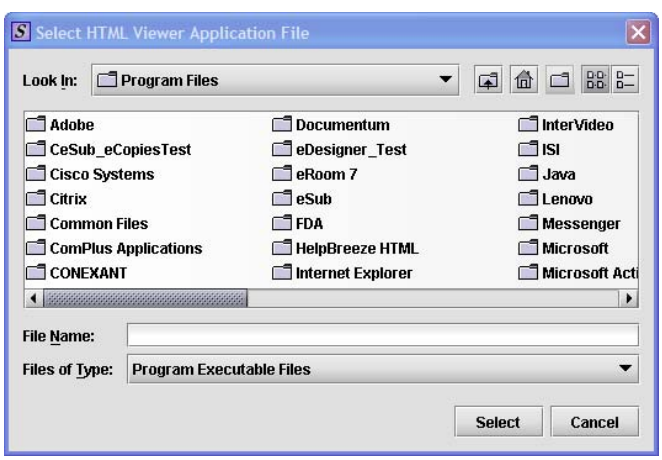
3. • Click in the **Look In** box to navigate to the **executable** (.EXE) of the application to view the HTML. For example, if you want to view the missing data output report in Word 2002, you would navigate using the following path:

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

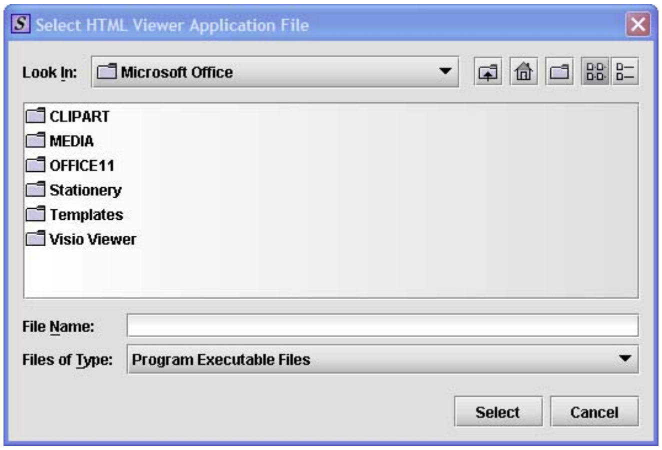
The following screens display an example for the navigation sequence to find Word 2002's executable (winword.exe):



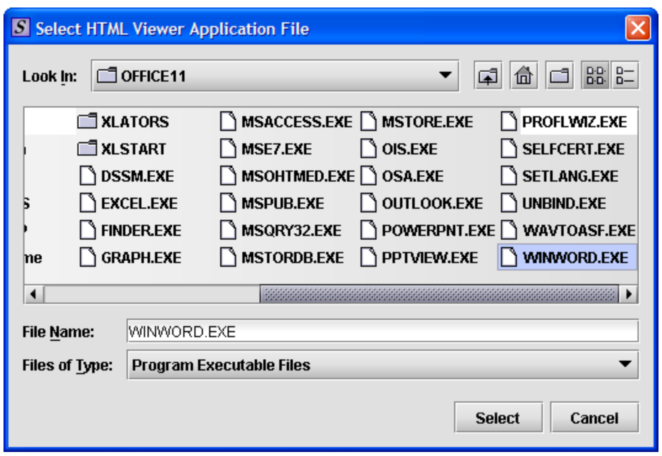
Finding Word's Executable File (Navigation 1)



Finding Word's Executable File (Navigation 2)



Finding Word's Executable File (Navigation 3)

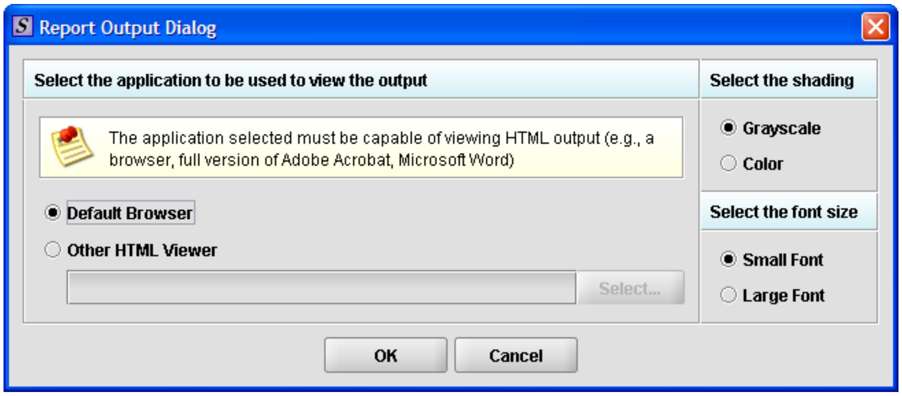


Finding Word's Executable File (Navigation 4)

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

Continued on Next Page

Report Output Dialog Box



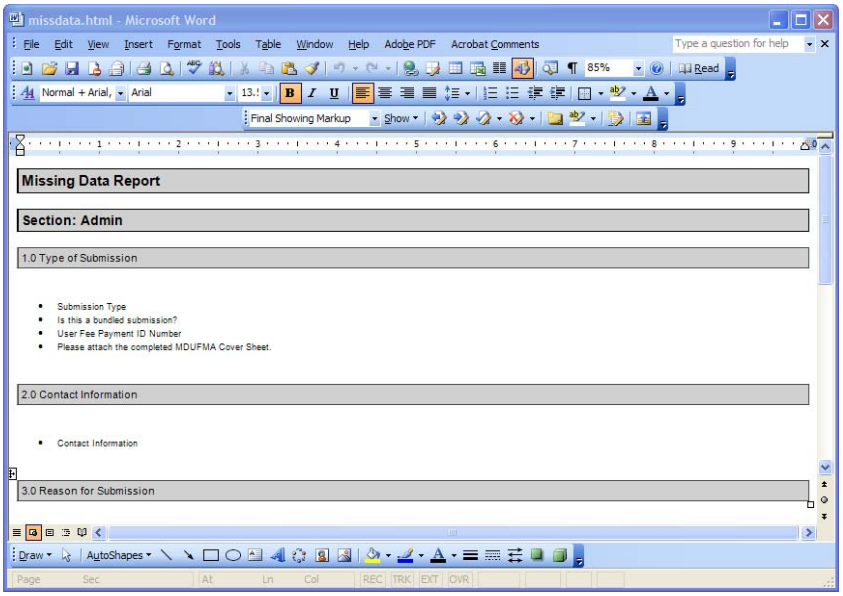
5. Select the desired shading of the report: lick the option button for **Grayscale** or **Color**.

6. Select the desired font size: lick the option button for **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).	

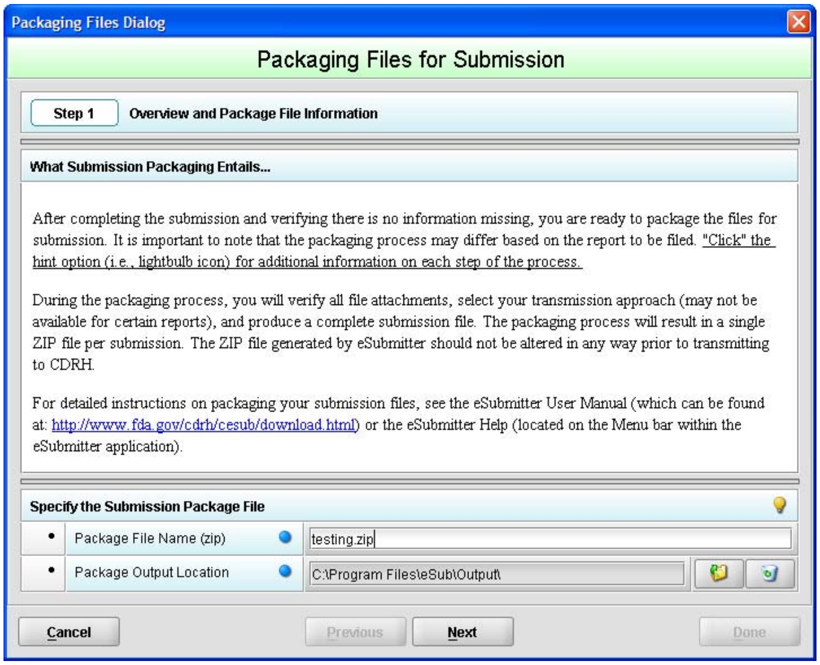
Warning

	Action	Graphic
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.	

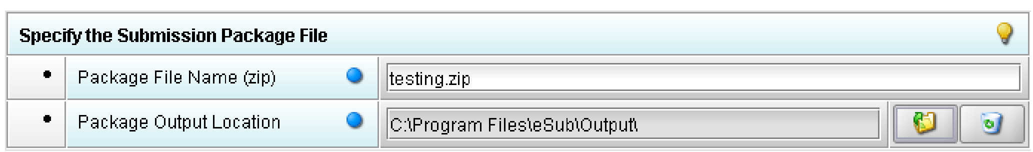
Continued on Next Page

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**.

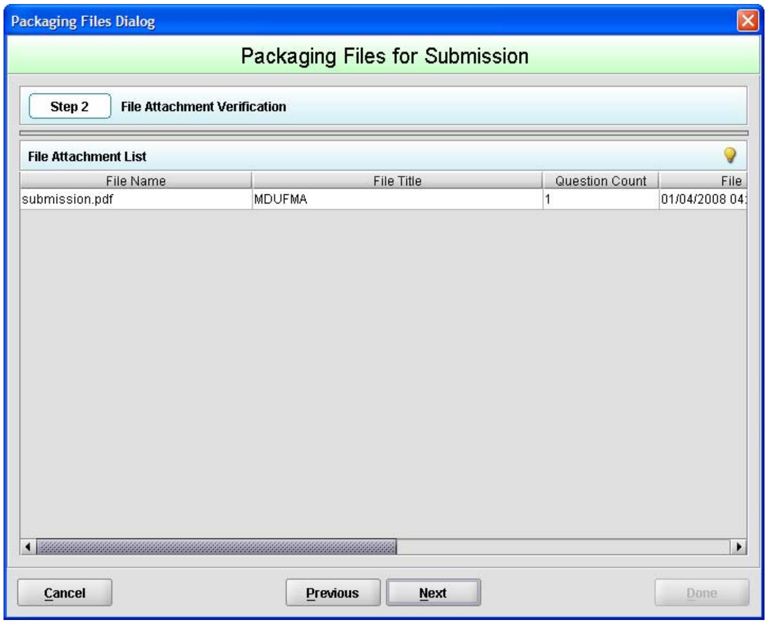


3. Click **Next** to proceed to *Step 2: File Attachment Verification*.

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

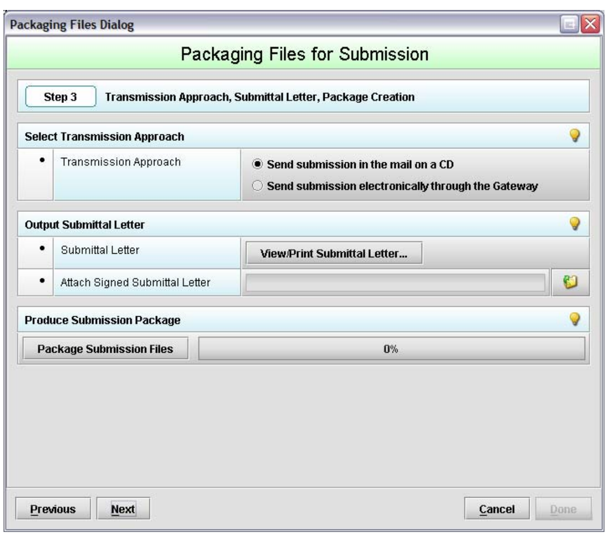
Click **Previous** to go back to **Step 1.**

OR

Cancel and exit the *Package File Dialog box*.

Step 3: Transmission Approach, Submittal Letter, and Packaging

This section will differ based on the report 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**.



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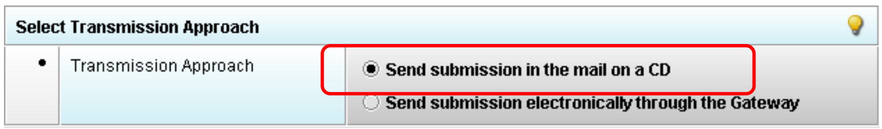
Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

Select Transition Approach (May or may not be available)

Choose the selected approach to send your submission to CDRH.

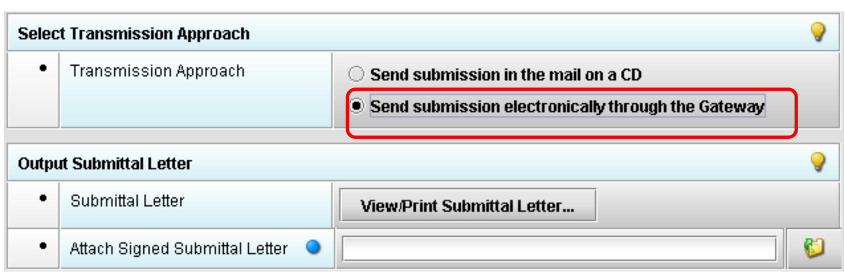
- The first approach is the traditional CD and signed cover letter mailed to CDRH. See below for an example.



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

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



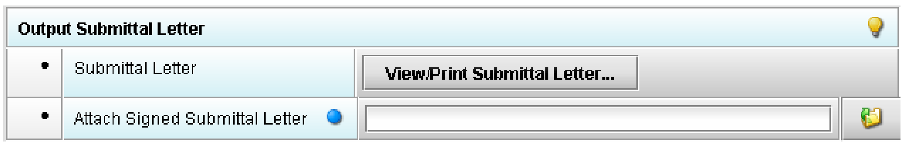
Output Submittal Letter (May or may not be available)

Follow the instructions below for the Output Submittal Letter.

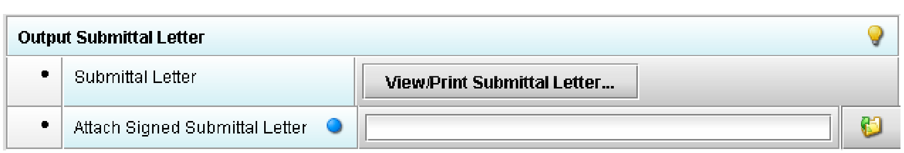
Continued on Next Page

Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

Action	Graphic
1. Click the  button, as shown below.	



Action	Graphic
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.	



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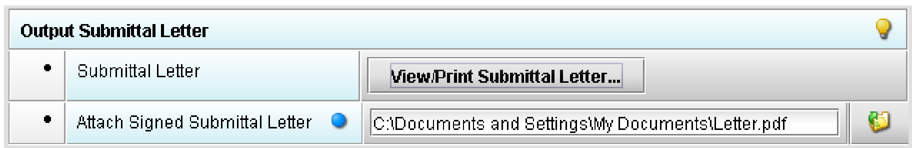
Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

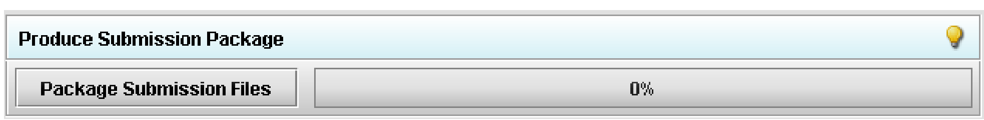
4. Once you have located the signed cover letter, click **Select** to attach the file to the packaging dialog box. The signed cover letter path should appear (as shown below).



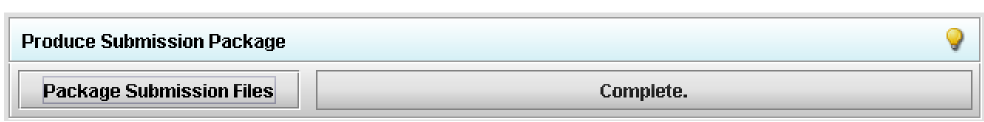
Produce Submission Package (Always available)

To produce a submission package, follow the instructions below.

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



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



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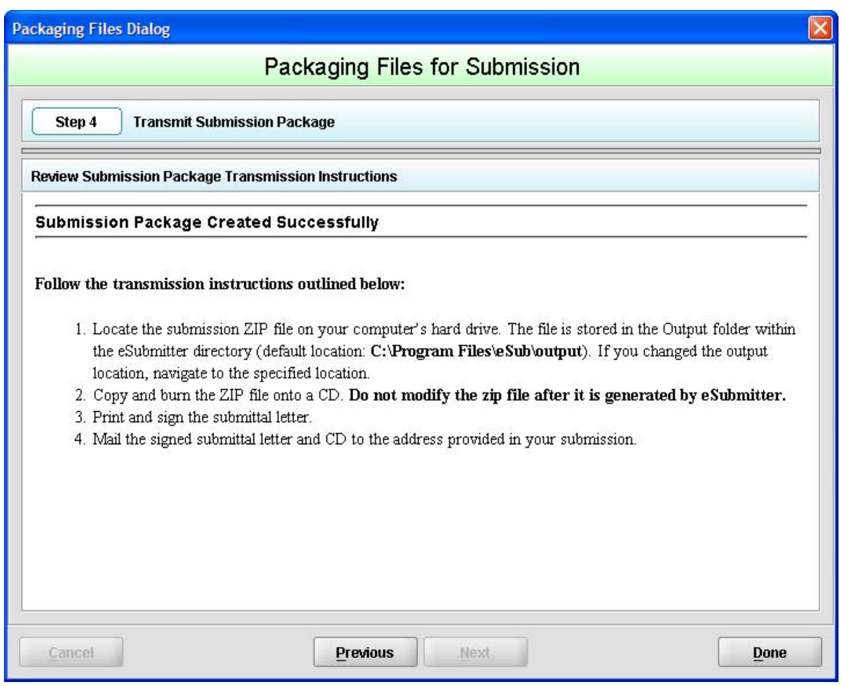
3. Click **Next** to proceed to **Step 4** to view the transmission instructions related to your submission.

Step 4: Transmit Submission Package (Always available)

This section provides confirmation that the submission files have been successfully packaged. The submission is ready to be sent to CDRH. 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 available). See below.	

Transmit Submission Package



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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:)**.	

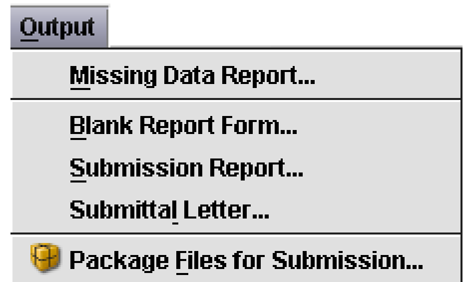
Subsection 4.3.1: Completing a Submission (Packaging Submission Files)

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 CDRH, see *Completing a Submission* on page 77.



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.

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 create a submission file to submit to CDRH until there is no missing data. For complete information, see *Completing a Submission* on page 77.
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 CDRH.

Section 6: User Support

Introduction

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

Section 7: Frequently Asked Questions

Question: As CeSub eSubmitter requires Windows OS, Adobe Reader 5.0 (or full Adobe Acrobat), and a CD-R, does it require any special permissions for a user on a Win2K/WinXP machine? What exactly does jinstall.exe unpack?

Answer: The CeSub eSubmitter application is based on Java. The installation program will unpack the application into the user designated location. All files installed will reside in the aforementioned designated location. The files installed include the application and support files, a Java runtime engine (JRE 1.4.2), and install/uninstall information. The JRE installed is specific to this application and should not interfere with other possible JRE's installed (i.e., JRE is not recognized by the OS but instead called by the eSubmitter application directly). The install program will setup menu short-cuts as well as provide uninstall information to the OS, which will require access to the Windows registry. Otherwise, no additional permissions should be required.

Question: Does eSubmitter introduce any new DLLs?

Answer: No.

Question: Does Submitter require any specific version of DLLs that are standard on the machine?

Answer: No.

Question: Does eSubmitter communicate outside the local box? Does it use any TCP ports?

Answer: Yes. The application uses an internet connection to perform auto-updates of the application and support files (e.g., enhancements, fixes). The auto-update process is called at start-up every time the application is executed. However, if no internet connection is available the application will still execute correctly but no updates will be received. If you use a proxy server there are settings within a configuration of the application to give the application permission to contact its auto-update site.

Question: Does eSubmitter introduce any vulnerabilities that you (the developers) are aware of?

Answer: None that we are aware of.

Question: Are there any issues I should be aware of that might affect our environment?

Answer: None that we are aware of.

Continued on Next Page

Section 7: Frequently Asked Questions

Question: Can I install the software on a network?

Answer: Yes. The software can be installed anywhere and will work properly. A new file locking option has recently been added to the software to prevent users from accidentally overwriting the work of another. For details, see *Networking* in *Preferences* on page **Error! Bookmark not defined.**.

Question: I have a PDF that I want to include. Can I add it the WinZip file generated by eSubmitter?

Answer: No. Do not modify the file after it is generated by eSubmitter. If you do modify a file, your submission will fail our loading process. You will have to repackage your files and resubmit the submission to CDRH. Always attach the desired PDF to the appropriate question.

Question: I sent my submission to CDRH, but was notified by a CeSub team member that something was wrong with my submission. I fixed the problem, repackaged the submission, and created a new CD. Is that all I have to do?

Answer: No. Be sure to print out a new submittal letter, sign this new letter and include with your resubmittal.