Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: <a href="https://occd@fda.hhs.gov">occd@fda.hhs.gov</a> and include 508 Accommodation and the title of the document in the subject line of your e-mail.

# eSubmitter Quick Guide

The eSubmitter software enables the electronic submission of regulatory information to FDA. At this time, eSubmitter may be used to submit the following to CDER: GDUFA submissions, to CDRH: Medical Device ISO 13485, Radiological Health Reports and Correspondence, OIVD 510(k)s, eCopies, and the MedWatch 3500A form for medical device adverse event reports, to CBER: Biologics Licensing Applications, and ICSR Adverse Event Reporting, to CTP: Tobacco Product Listing, Health Data, and HPHC submissions, and to CVM: All pre-market ONADE submissions for New Animal Drug Applications, Abbreviated New Animal Drug Applications, Investigational New Animal Drug Files, General Correspondence Files, and post-market OSC DER submissions. This quick guide will instruct you on the basics for using the application as each Center's application differs slightly. For more specific information, please refer to the full length <u>eSubmitter User Manual</u>.

#### Inside this guide:

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🦸 🛛 = Important Tip	
Emportant Warning	

#### eSubmitter Icon Directory:

- Required Response
   Helpful Tip
   Information Message
   Error Message
   Note Message
   Stop Message
   Warning Message
   Confirmation Message
- = Critical Required Response

### Access the Software

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

- Go to the Start menu and select Programs > FDA Submission Software > eSubmitter.
- 2. You will see a *Registration Dialog box* (as shown to the right).
- Click <u>Next</u> to continue the registration process.
   Or, click <u>Register Later</u> to register at another time.

If you click wext, you will see a *Registration Dialog box*. If you choose to register, move forward through the wizard, and enter all requested information.



- 4. The registration wizard will prompt you to check results of the registration. If there was a problem generating your email, select the radio button **No there was a Problem** and follow the instructions provided. If your email was sent, select **Yes the Email was sent successfully**.
- 5. Click Done when you are finished. The dialog box will close.

### **Getting Started**

The *Welcome Screen* will be displayed (as shown below). The contents and tools available in the *Welcome Screen* are described in the table on page 2.



Function	Icon	Description
Create New Submission		Allows you to create a new submission entry. The <i>New Submission Data Dialog</i> box will appear. See section <i>Creating a New Submission</i> for more detailed information.
Open an Existing Submission	6	Allows you to open an existing submission. The <i>Open Submission Data Dialog</i> box will appear. See section <i>Opening an Existing Submission</i> for more detailed information.
eSubmitter Quick Guide	2	Launches the eSubmitter Quick Guide. If the Quick Guide does not contain the information you are searching for, see the full length <u>eSubmitter User Manual.</u>
Exit Application	-{]	Closes the eSubmitter application.
Help Topics	2	Displays the <i>Help Menu</i> , which provides instructional information and support for utilizing the eSubmitter application.
Forward Navigation Arrow		This arrow allows you to move forward through the <b>Message Tabs</b> .
Backward Navigation Arrow		This arrow allows you to move backwards through the <b>Message Tabs</b> .
Collapse/Expand Arrows	1	Allows you to collapse and expand the <b>Menu Options</b> portion of the <i>Welcome Screen</i> .
Notification Stars	会	The yellow stars are intended to notify users when new messages are available. The star ap- pears next to the message tab header with new unread messages.
Category Catergory Filter: Show	All 🔻	Allows you to filter the message information to display only generic information or those mes- sages pertaining to a particular program. eSubmitter will remember the selected filter option upon closing and reopening the application.
Mark as Read 🗌 Mark as I	Read?	This checkbox enables you to indicate which message tabs have been read. Mark this checkbox to remove the yellow star shown next to the tab header. Unmark this checkbox to make

the yellow star on the applicable tab header reappear.

#### The contents of the Welcome Screen are described in the table below.

### **Set User Preferences**

eSubmitter is initially installed with default preferences that can be altered at any time.

- 1. To view or update your setup preferences, select File > Preferences.
- 2. The User Preferences Dialog box appears as shown to the right. Each category in the User Preferences Dialog box is explained briefly below.

Auto Save: Allows automatic saves of reports while you work. You can also set the save interval which has a default interval setting of 10 minutes.

Layout: Allows you to set whether you want eSubmitter to open reports in the Simple Layout or Expert Layout when you start up the application. At default, eSubmitter opens reports in the Simple Layout.

	Layout	Networking	File Location	File Viewer	Messages	Memory	
Preferen	es related t:	o the automatic	on of saving data	within a timed	l interval		
Enable	auto-save						×
•	Time interval	l between saves	s (minutes)				• 10

**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 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.

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).

File Viewer: Allows you to identify the application that you will use as your PDF viewer. (Generally, Adobe Acrobat is used)

**Messages**: Allows you to indicate whether you will receive missing data message when leaving a screen. Memory: Allows you to identify how much memory will be allocated when the application starts (default: 2MB) and how much memory will be made available, as needed (default: 64MB).

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

For more detailed instructions on setting your user preferences, see section 2.2 of the eSubmitter User Manual after download.

### **Create a New Submission**

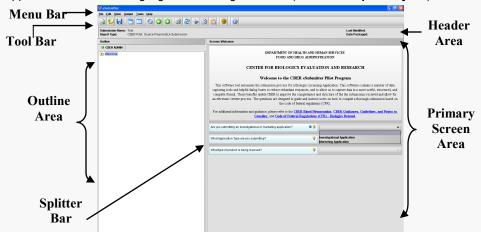
🔒 Create New Submission...

Follow the next steps to create a new submission from scratch:

- 1. The eSubmitter application should be open on your computer desktop. If it is open, and you see the **Welcome Screen**, go to step 2. (If it is not open, open the application first by following the instructions in *Access the Software*.)
- 2. Click the Create New Submission button from the Menu Options.

Or you may select **File > New** or, click the **New Report** icon (<sup>[]</sup>) on the **Tool Bar**. The *New Submission Dialog box* is displayed (as shown to the right).

- 💈 Click on the **yellow light bulb** ( 💡 ) to view helpful hints.
- Step 1. Select a Submission Type. The New Submission Dialog wizard is comprised of two parts. The first section (top portion of the window) requires that you select which Submission Type to create. When you click on the Submission Type, the bottom portion of the window displays information related to the corresponding submission type. (See screen shot to the right.)
- Once you have selected the Submission Type, click Step 2. Provide Submission Details appears (as shown to the right).
- 5. Complete the fields in this dialog box as follows:
  - Descriptive Name Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (A required Entry is indicated by the blue dot.)
  - File Name Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.) File names should not contain more than 100 characters. Do not use symbols when naming the file(s).
  - Additional comments Enter any additional information about this report (Optional Entry).
- 6. When you are finished entering all of the information, click
- 7. The first screen of your new blank submission is displayed.
- 8. The parts of the application window are highlighted in the figure below (shown in Expert Layout).



Create

9. You are now ready to complete this submission. Go to Entering Submission Information.

To learn how to copy an existing submission to create a new submission, refer to section 2.4 of the eSubmitter User Manual after download.

#### New Submission Dia Create New Submission Step 1 Select a Submission Type 0 List of Available Submission Types Version Version Date 12/09/2008 09:44:10 / CBER Pilot: Source Plasma BLA Submissio In Vitro Diagnostic Device - 510(k) 08/28/2008 04:02:16 MedWatch Form 3500A (OMB No. 0910-0291) 11/05/2008 09:52:6 A Radiation Emitting Product (OMB No. 0910-0025) 1.3 12/05/2008 11:46:40 / Report of Assembly of a Diagnostic X-Ray System 11/05/2008 04:20:43 F Description of Selected Submission Type **CBER eSubmitter Pilot Submission** The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) initiated the CBER eSubmitter Pilot program to enable Industry to voluntarily submit Source Plasma Biologics Licensing Applications (BLA) electronically. The eSubmitter tool enables pilot participants to electronically complete and submit a BLA for Source Plasma to CBER's Office of Blood Research and Review (OBRR). This is a pilot program designed to gather industry feetback on the eSubmitter electronic submission initiative and determine if this mechanism is a benefit to both the blood industry and the FDA. For additional information on Cancel Next Create

	Create New Submission		
Step 2 Provide Submiss	ion Details		
pecify the Submission Descript	ve and File Names	(	
<ul> <li>Descriptive Name</li> </ul>	•		
File Name (xml)			
dditional Comments about this S	ubmission	(	

### **Open an Existing Submission**

😏 Open Existing Submission.

Follow the next steps to open an existing submission:

- 1. The eSubmitter application should be open on your computer desktop. If it is open, and you see the **Welcome Screen**, go to step 2. (If it is not open, open the application first by following the instructions in *Access the Software*.)
- Click the Open Existing Submission button from the Menu Options. Or you may select File > Open or, click the Open Submission icon () on the Tool Bar.
- 3. The *Open Submission Dialog box* will be displayed (as shown to the right).
- 4. This dialog box allows you to select an existing submission or begin a new one. As you create new reports, they will be 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.
- 5. Look at the bottom of the *Open Submission Dialog box*. You will see four option buttons that are described below:
  - Create New Submission...: Clicking this button displays the New Submission Dialog box, which allows the creation of a new submission report file. See Create a New Submission.

S Open Submission Dialog		X
Open Existing S	Submission	
Select a Submission to Open		
Submission Name	File Name	Last M
Test	Testxml	
- [		
		•••••
View the Description of the Selected Submission		
Create New Submission	Open	Cancel

- Open: Clicking this button closes the Open Submission Dialog box, and opens the selected submission. In addition, double-clicking on a submission or pressing the Enter key while a sub
  - mission is highlighted will also open the submission.
- Cancel: Clicking this button closes the Open Submission Dialog box with no changes to the screen.

### **Enter Submission Information**

#### Enter Responses into the Submission

- 1. The eSubmitter application must be open on your computer desktop, and a submission must be open.
- 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 by double clicking on the section name to load the questions. You may also use the navigation arrows to move forward or to a previous section.
- 3. Provide a response to the question(s) on the screen (required entries are indicated by the blue dot). The response required depends on the type of question. See *Complex Question Types* for instructions on entering information into the various types.

*f* you do not finish entering information into a submission in one session, you may return to it at another time. See Save Submission sion Entries or Changes.

### Save Submission Entries or Changes

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.

- 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.
- 1. Click File > Save OR
- 2. Click 🛃 on the **Tool Bar**. The submission data has been saved.

To close and exit the application see Closing and Reopening a Submission.

## **Closing and Reopening an Existing Submission**

#### To Close a Submission:

• Click File > Close. The submission closes and the Welcome Screen is displayed.

Exit Application

#### To Reopen an Existing Submission:

- Click File > Open on the menu bar or Open Existing Submission...
   from the Menu Options Pane. You see the Open Existing Submission Dialog box.
- Click to select (highlight) the submission that you wish to open, and click select. The selected report is displayed.

#### To Exit the Application:

• To close eSubmitter, click

on the Menu Options Pane.

### **Complex Question Types**

The eSubmitter application uses various question types to capture all the information that is required for a specific submission. Several of the eSubmitter question types are complex in nature. The purpose of this section is to provide a brief overview of all of the various complex question types that are used in the eSubmitter.

This section describes each of the different complex question types and includes examples of their respective responses. You may not see all of these types of questions in one particular report.

**Contact Question Types:** This question type contains various contact related fields that you need to complete.

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 Book**.

When you enter the information directly (without using the **Contact Book**), the contact information is only saved for the submission. However, you should use the "**Copy To**" **Contact Book** feature if you have already entered data into the field directory and would like to store the information for future use. Copying the information from the **Contact Book** saves time for data entry because the information is automatically copied into the question. Information in the **Address Book** and **Contact Book** require that you only enter data once and reuse it across submissions.

#### Copy Information from Contact Book into Contact Question

- 1. Click the **Copy from Contact Book** icon ( ) in the question. The *Contact List Dialog box* is displayed (as shown to the right).
- 2. Click to highlight and select the desired contact.
- 3. Click select . The contact information is automatically populated in the different entry areas.
- $\frac{3}{2}$  If the information is not exactly the same, you can edit the data after copying it.

#### Copy Information Up from Contact Question into Contact Address Book

If you have already entered data into the field directory and would like to store the information for future use, follow the instructions below to copy it into the **Contact Book**.

- 1. Click the **Copy to Contact Book** icon () in the question. The *Confirmation dialog box* will be displayed (as shown to the right).
- Click Yes to copy the information to the Contact Book. Click
   No if you do wish to copy the information.
- If you choose to copy the information, a message will appear, stating, "Contact information successfully copied to the Contact Book." You may now reuse the stored information by copying it from the Contact Book.
- The Address Book feature works similarly to the Contact Book described above. To enter and store information in the Address Book and/or Contact Book for use across submissions, open the book from the Tools menu . You may also copy this information into your Address/Contact Books directly from questions using the Copy Information Up feature described above.

elect the Responsible In	dividual from the Conta	ct Address book:	9 🐻 (	<b>2</b>
Contact Identification	Establishment Identi	fication Physical Loc	cation Mailing Location	n
Contact				
Title (Mr., Ms., Dr.):				
First/Given Name:	•			
Middle Name:				
Last Name:	•			
Occupation Title:				
Email Address:	•			

Contact Name	Occupation Title
Lavelle, Don	
Sinkavitch, Hope	
Velezis, Marti	
۲	
Instantiation View comments on the selected contact	

onfirm	ation 🔀
?	Copy the Contact Information from the selected response to the Contact Address Book?
	Yes No

**File Attachment:** This question type allows you to attach a document file as a response. The question may contain a text editor that allows or requires you to type additional narrative to supplement the attachment. 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. You may be required to provide 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. Once identified, the software will no longer prompt for this information.

To the right is an example of an attachment question with a response entered. eSubmitter allows you to attach files that are PDF, Excel, XML, ZIP, SGML, XPT, MOL, DTD, GIF, TIF, JPG, WMV and AVI files. However, the question itself may be restricted to only allow certain file types to be attached (e.g., PDF only or a combination, such as PDF and/or Excel file types only).

This section of the quality assu	urance summary shall include those	individuals with the authority to ac	t, to report, or to recom	mend. 🔍 🔍
🤣 💻 🔍				1 item in the list
Title	Name	Date	Size	
est Document	QA_test.pdf	12/08/2008 11:36:46	AM 7 KB	C:\Docum
Details				

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 File to Attachment Question

- 1. Click the **Add File** icon ( ) to open the *File Attachment Dialog* (as shown to the right).
- 2. Step 1: Select the Method for Identifying the File to Attach.

Choose the desired method for selecting the file to attach. The options are:

- Choose a previously attached file from a master list OR
- Select a new file from your computer or a network drive that has not been previously attached to the submission.

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

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

File Attachment Dialog					(
Atta	ich File to Respons	e			
Step 1 Select the Method for Identifyin	g the File to Attach				9
Select a File from a List of Previously Attached Files     Select a New File from the Workstation or Network					
Step 2 Select the File to Attach from th	e List				9
List of Previously Attached Files			<b>Q</b>		0
Title	Name	Question Count		Date	9
Sample	(S(anhpt045fbojworgskkgo	1	02/19/2	009 08:5	7:11 🗗
<ul> <li>▲ I file in the list.</li> </ul>					
General Description of the Selected Files					
Close w/Changes					

- 3. Step 2: Select the File to Attach According to the Method Chosen -- Select a File from a List of Previously Attached Files. If the file can be located in the list of previously attached files, select (highlight) the file.
- 4. Once a file in the list is highlighted, the Attach Selected File button is activated in the bottom right side of the dialog box. Click the Attach Selected File button to properly attach the selected file to the question response.

Attach Selected File

 Step 2: Select the File to Attach According to the Method Chosen -- Select a New File from the Workstation or Network. If the file cannot be located in the master list, then the method chosen in Step 1 must be "Select a New File from the Workstation or Network".

(Continued on Next Page)

#### Attach File to Attachment Question (continued)

- The available fields in Step 2 of the File Attachment dialog changes to correspond with the method chosen (as shown to the right).
- 7. Click the **file folder** icon (<sup>12</sup>). You will see a Select File dialog box (as shown below, left).
- Click in the Look In drop-down menu to locate the drive, such as Local Disk (C:), or folder where the PDF is stored.
- When you locate the desired PDF, click to select it (highlight). The name of the file appears in File Name.
- 10. Click Select . The Select File dialog box closes, and you return to New File Dialog box (as shown below, right). The Name, Path, Date, and Size fields will be populated with the specifications from the file you have just selected.
- 11. Enter a title in **Descriptive title** (required entry) and a description in **General description**, if desired.
- 12. Click OK You will return to the *File Attachment Dialog box*. The file that was added is automatically selected in the list of files.

File Attachment Dialog					
Attach File	to Response				
Step 1         Select the Method for Identifying the File to Attach         Image: Provide the Method for Identifying the File to Attach					
○ Select a File from a List of Previously Attached Files ● Select a New File from the Workstation or Network					
Step 2 Locate the File to Attach	<u> </u>				
Locate File	<u> </u>				
Descriptive Title					
Language	<b>•</b>				
General Description of the Selected Files					
Close w/Changes	Attach Selected File				

13. Click <u>Attach Selected File</u>. You will now see the path (location) of the file on the network drive or hard drive of your computer appear in the file attachment question.

S Select File	S New File Dialog
Look In: eSub data JExpress manual META-INF	Select a File       Name       Path       Date       Size
Cutput	Descriptive   Language
File Name:	General description OK Cancel Help

Multiple File Attachments: This question type allows you to attach multiple files as a response. Below is an example of an attachment question with a file attachment included. Note that the attach file icon ( ) is still enabled after attaching a file, indicating that additional files may be attached as part of the response.

				1 item in the I
Title	Name	Date	Size	
Test Document	SOP_test_1.pdf	12/08/2008 11:17:55 AM	7 KB	C:\Docun

#### Attach Multiple Files to Attachment Question

To attach multiple files to a multiple file attachment question type, see the same instructions listed under the instructions for how to Attach File to Attachment Question, beginning on page 6 of this guide. Repeat these steps to attach multiple files.



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

1. Click the **Select Item** icon (

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

U.S. Food and Drug Administration

Protecting and Promoting Your Health

- 2. Click to select (highlight) the desired option.
- 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 on right).
- 4. If you wish to change your response, click the delete icon
- 5. Repeat steps 1 through 3 to make another selection.

Select an item from with	in the list	
Identifier	Name	
000.0000	UNDEFINED	[
1020.10	TELEVISION RECEIVERS	
1020.30	DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS	
1020.31	RADIOGRAPHIC EQUIPMENT	
1020.32	FLUOROSCOPIC EQUIPMENT	
	1774 items in the list.	

Sections as Tables: Entire screens may appear as a table. This format is indicated by a row of buttons for Add 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 View List and View Detail tabs.

#### Add Entry to Tabular Section

1. Click the **Add** button to add an item to the table. You see a screen containing questions for you to answer (an example in the **List** view is shown below).

Select the type of unit

Select the unit of measure Select the quantity reporte

If "Other" type, specify further

Screen View	Screen View Listing of Ingredients: Product Identification								
	۹ 😣								
💠 Add	🚥 Delete	Delete Al			Detail	Info	)	ŵ	4
Table of Tobacco Pro	Table of Tobacco Products								
Item Prode	t Name Unique ID T	rpe of Unique ID	Product	l Tracking Number	Intended Use			Product Categ	ory

- 2. To see the details of an entry in the list, click **View Detail** (as shown to the right).
- If you accidentally enter a blank into the table, (by clicking Add New, not responding to any questions, and then clicking View Detail), you will see a blank line in the View List view. Select the line to be deleted and click the Delete button to remove the item from the table.
- 4. Click the **Delete All** button to delete all entries in the tabular screen.
- To navigate through the list of entries in the table, use the up and down arrows.
- Some tabular screens may be linked together through a parent/child relationship. If this parent/child relationship exists, you will see a header bar on the child screens indicating which list item within the parent table you are currently entering data for. These child screens will be repeated for each list entry in the parent table, as necessary (as shown to the right as a green header bar).

	V.	~							
🍄 Add	Celete Celete	Delete All	List	Detail	Info	Ŷ			
Item: 1 Tobacco Pro	duct Details								
Enter the product name (i.e.	, brand/sub-brand or other comr	nercial name used in commerci	ial distribution):		• •				
A product identification num	ber must be provided if needed	to uniquely identify the product							
<ul> <li>Select the type of pro</li> </ul>	Select the type of product identification number:								
If known, enter the FDA-ass	igned tracking number (e.g., TP#	*****	t		TP	_			
Select intended use of this	product				•				
Select the product category:					•				
<ul> <li>If Other, please desc</li> </ul>	ribe further:								
Screen View Listin	ng of Ingredients: Ingre	dient Identification							
							<b>?</b>		
							Pen		
roduct Sample Product									

**Guidance Documents:** This question type allows you to select FDA guidance documents 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

1. Click the **Add Guidance** icon (

S Guidance Document Filter Dialog								
Provide Guidance Document filter criteria (keywords)								
Title     Office     CDRH	•	Division						
Guidance Documents matching the specified filter criteria			View Guidance					
Title	Office	Division						
Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and	http://www.fda.gov/cd 🔺							
Bundling Multiple Devices or Multiple Indications in a Single Submission - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cd					
User Fees and Refunds for Premarket Approval Applications - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cd					
Expedited Review of Premarket Submissions for Devices - Guidance for Industry and FDA Staff	CDRH		http://www.fda.gov/cd					
B Guidance Documents in the filtered list.								
Guidance Documents currently selected			View Guidance					
Title	Office	Division						
Draft Guidance Document for 510(k) Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In Vitro Devices	OIVD	DIHD	http://www.fda.gov/cd					
Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and		http://www.fda.gov/cd						
			•					
2 Guidance Documents in the selected list.								
Clear Filter Select Delete		(	Cancel					

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.
- 2. 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.
- 3. Use the scroll bar to see information about the found guidance documents.
- 4. If you are connected to the Internet and have Adobe Acrobat installed, click to select a desired document and click View Guidance...
- 5. 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.
- 6. Click 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.

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

Product Code (Single): Applicable to CDRH only. 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 single product code question.

Choose the product code for this submission.					
Product Code					
Product Code Name					
Device Class					
Classification Panel					
C.F.R. Section					
Add any other product codes that a	are applicable to this submission.				

#### Add a Single Product Code

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 Product Code by Keyword

- 1. Click the **Select Item** icon (
- 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.
- 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 (
  - Click Clear Filter to remove entries and start the search over again.
- 4. Click to highlight the best match to your product/device, and click select. You product code question. The remaining fields in the question are filled in for you.

**Product Codes (Multiple):** Applicable to CDRH only. This question type allows you to identify other product codes applicable to the submission. To the right is an example of a multiple product code question.

#### Add Multiple Product Codes

- 1. Click the Add Product Code icon (...). You see the *Product Codes Filter Dialog box* (as shown below).
- 2. Enter **Product Code** and **Product Code Name** in the appropriate sections.
- 3. Click <sup>ok</sup>

Dialog		🔼				
filter criteria						
ame (keyword search)	1					
		•				
anel		<b>~</b>				
C.F.R. Section						
		🕹 📼				
es						
Produ	uct Code Name	Device Class Cla				
		1				
		•				
0 Pi	roduct Codes in the list.					
Clear Filter Select Cancel						
	ame (keyword search) anel es Prod	Ifter criteria Inter				

You retur	n to the	submission	screen	and	the

S Product Code Filter	Dialog							
Provide Product Code f	ilter criteria (keywords)							
Product Code	Product Code	le Name						
Device Class	<ul> <li>Classification</li> </ul>	in Panel	-					
C.F.R. Section		1						
Identifier		4						
Name								
Product Codes metching the specified filter criteria           Product Code         Product Code Name           Device Class         Classification           4								
Product Codes current	-							
Product Code Product Code Name Device Class Classificatio								
4								
	0 Product Codes in th	the selected list.						
Clear Filter S	elect Delete	ОК	Cancel					

#### (Continued on Next Page)

#### Search for Multiple Product Codes by Keyword

- 1. Enter a keyword in **Product Code Name** to search the database. You will be provided a list of product codes from which to choose in the in **Product Codes matching the specified filter criteria** portion of the dialog box.
- 2. To further refine your search, if desired:
  - Click the Device Class drop-down list and make a selection.
  - Click the Classification Panel drop-down list and make a selection.
  - Click the **Select Item** icon (
  - Click Clear Filter 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 cur**rently selected.
- 4. Repeat steps 1 and 2 to continue to add product codes.



- 5. Click to return to the multiple product codes question, which shows your selections.
- Standards: Applicable to CDRH only. This question type allows you to select a standard for your submission from the CDRH list of recognized standards.

#### Add a Standard

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

E	Star	ndards Filter Dialog					X
	Prov	ide Standards filter c	riteria (keywords)				
	•	Title/Reference		Category	-	Organization	-
ľ	Stan	dards matching the s	pecified filter criteria				
			Title and Reference N	umber		Category	Organizat
							-
	4 888		0 Sta	andards in the filtered			
		dards currently selec	tod				
	3401	uarus currentiy selec	Title and Reference N	umber		Category	Organizat
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							-
	4			ndards in the selecter	t liet		•
				nuarus in the selecter	J 1101.		
	Cle	ear Filter Sele	ct Delete			ОК	Cancel

- 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 Clear Filter to remove entries and start the search over again.
- 4. Click to highlight the best match to your product/device, and click select. The standard appears in **Standards matching the specified filter criteria**.
- 5. When you are finished adding standards, click . You return to the standards question.

### **Check Completeness of Submission**

To check for completeness of a submission, you must identify if any data is missing from your report (and then enter the required data), and package the files for submission.

You will only be able to package files for submission if all required fields have been completed in 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.



All submission 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.

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

S Report Output Dialog	
Select the application to be used to view the output	Select the shading
The application selected must be capable of viewing HTML output (e.g., a browser, full version of Adobe Acrobat, Microsoft Word)	<ul> <li>Grayscale</li> <li>Color</li> </ul>
Default Browser	Select the font size
Other HTML Viewer	Small Font
Select	C Large Font
OK Cancel	

- 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 11> WINWORD.EXE
- 4. Click Select . You return to the Report Output Dialog box with your selection showing.
- 5. Select the desired shading of the report: click the option button for Grayscale or Color.
- 6. Select the desired font size: click the option button for Small Font or Large Font (which is approximately 10 pt).
- 7. When you are finished making selections, click 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.

🔊 missdata.html - Microsoft Word 📃 🗖	×
Ele Edit View Insert Format Tools Table Window Help Adobe PDF Acrobat Comments Type a question for help	- ×
🗄 🞯 😡 💪 🖂 🚳 🛆 🖤 📖 🙏 🖻 🎕 🛷 🕫 - 🔍 - 🧐 🖓 🎟 🖓 🖓 📲 🚱 🖓 📲 🚱	
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Missing Data Report	
Section: Admin	-
1.0 Type of Submission	
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8. After you have verified that no data is missing from the submission, you are ready to package your files for submission.



### **Package 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. *Please note these steps will differ based on the submission you are filing.* 

- 1. Click **Output > Package Files for Submission** from the menu bar.
- 2. If data is missing, a warning message will be displayed.
- 3. If the submission has all required data, the *Packaging Files Dialog box* is displayed (as shown to the right). Within the *Packaging Files Dialog box* you will be prompted to move through a series of steps detailed below.

### Step 1: Overview and Package File Information

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

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.
- Specify the submission output location.
  - The **Package Output Location** identifies the file folder where the zip file is located. Make a note of the output location.
  - To change the location click the file folder icon, locate the desired location and click
     Select
- 3. Click to proceed to Step 2: File Attachment Verification.

#### Step 2: File Attachment Verification

This section lists all file attachments used in the submission.

- Check the list to ensure that all of the appropriate file attachments are listed (only files referenced in responses will be included). See to the right for an example.
- 2. Check the question counts to confirm that the files are attached properly as question responses.
- 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.

File Attachment List		
File Name	File Title	Question Count
submission.pdf	MDUFMA	1 01/04/200

- 3. Check the file dates, size, and locations to ensure the correct versions of the files are provided.
- 4. Click to proceed to Step 3: Submittal Letter, Package Creation and continue packaging the submission.

#### Step 3: Submittal Letter, Package Creation

*This step will differ based on the submission you are filing.* Some programs accept digital signature and submission via the Electronic Submissions Gateway and others require submission via CD-ROM and handwriting signatures. The required activities in Step 3 will differ based on the applicable program.

For further details, see Packaging and Transmission Guidelines for Participating eSubmitter Programs on page 15.

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*. An example of what may appear in *Step 3: Submittal Letter, Package Creation* is shown to the right.

	Packaging Files for Submission	
Step 3 Submittal Lette	er, Package Creation	
utput Submittal Letter		9
Submittal Letter	View/Print Submittal Letter	
roduce Submission Package		Ŷ
After completing all step for submission.	os to this point, click the "Package Subnmission Files" button I	below to begin creating the file
Package Submission Files	0%	
Cancel	Previous	

Packaging Files Dialog 🔀
Packaging Files for Submission
Step 1 Overview and Package File Information
What Submission Packaging Entails
After completing the submission and verifying there is no information missing, you are ready to package the files for submission. It is important to note that the packaging process my differ based on the rejord to be filed. <u>'Clicke' the</u> , thin option (i.e. alphtuble ion) for additional information on each step of the process. During the packaging process, you will verify all file attachments, select your transmission approach (may not be available for certain reports), and produce a complete submission file. The packaging process will result in a single ZDF file per voluming into the generated by eSubmitter should not be altered in any way prior to transmitting to CDRH. For detailed instructions on packaging your submission files, see the eSubmitter User Manual (which can be found at <u>the places (dagsychickes) download hind</u> ) or the eSubmitter application).
Specify the Submission Package File
Package File Name (zlp)     testing.zip
Package Output Location     CtProgram FilesteSubtOutputt
Cancel Previous Next Done



#### **Output Submittal Letter**

- 1. Click View/Print Submittal Letter...
- 2. Ensure that your submittal letter is accurate.
- 3. Print and sign the submittal letter.
- 4. Prepare to mail the submittal letter (for CD transmission approach)
  - OR

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).

- 5. Click the **folder** icon ( $\stackrel{[]{}}{=}$ ) to attach the signed submittal letter that has been scanned.
- 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.

#### Produce Submission Package

1. Click on Package Submission Files to initiate the packaging of the ZIP file.

Once the submission has packaged successfully, the status bar will indicate that the packaging is complete.

- Very large submissions may be broken up into multiple packaged zip files. As a result, a confirmation statement will be displayed (as shown on the right). Close the confirmation statement and proceed to Step #2.
- 2. Click to proceed to Step 4: Transmit Submission Package to view the transmission instructions related to your submission.

format	tion 🔀
B	The submission was packaged successfully. However, due to the size of the content it was split into multiple separate files.
	Please make sure to include all of the following files when submitting to FDA: C\Documents and Settings\eSub_Home\package\Ti0000387_001 zip C\Documents and Settings\eSub_Home\package\Ti0000387_002.zip C\Documents and Settings\eSub_Home\package\Ti0000387_003.zip
	The submission will be incomplete until all files are received by FDA. If you have questions, please contact the eSubmitter Help Desk at esubmitter@da.hhs.gov
	Close

#### Step 4: Transmit Submission Package

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

- 1. Read the instructions provided (as shown to the right). These instructions may vary depending on the program to which you are submitting.
- For further details, see Packaging and Transmission Guidelines for Participating eSubmitter Programs on page 15.
- 2. Click Done Click Previous

to close the *Packaging Files Dialog box*. OR

to return to Step 3: Submittal Letter, Package Creation.

	Submission Package Transmission Instructions
-	the transmission instructions outlined below: . Locate the submission ZIP file on your computer's hard drive. The file is stored in the Output folder designated within eSubmitter (i.e., the Output location specified under File>Preference). C Goys and burn the ZIP file onto a CD. <b>Do not modify the rip file after</b> it is generated by eSubmitte R. Print and sign the submittal letter and CD to the address provided in your submission.
	The active of the second

#### Locate the Submission Files on the Computer's Hard Drive

- 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. Below is a list of the most likely locations for the submission files, based on the installation location and operating system.
  - If installed on a Network drive (Windows XP or earlier): The location of your data and output files will be contained within the eSub directory where the application was installed.
  - If installed on a Workstation (on Windows XP or earlier): data and output files should be hosted in the following location: C: \Documents and Settings\eSub\_Home\.
- If you still cannot locate the submission files, check within your User Preferences, by navigating to **File > Preferences > File Lo-Cation**. The **Output Location** field will specify exactly where the submission files are located.
- 5. Navigate to the appropriate location.
- 6. 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.
- 7. Follow the transmission instructions for the program you are submitting to. See *Contacts and Addresses* tab on the *Welcome Screen* for more information on how and where to send your submission.

### Packaging and Transmission Guidelines for Participating eSubmitter Programs

As of May 2015, the following is acceptable for each participating program regarding digital signatures and the FDA Electronic Submissions Gateway (ESG). Please verify with the FDA program website that these guidelines have not changed. Program websites are accessible from the <u>eSubmitter home page</u>.

#### CDER Programs:

• <u>Generic Drug Facility Electronic Self-Identification</u>: Digital signatures are not accepted at this time for GDUFA submissions. The CDER program only accepts submissions via the FDA ESG.

#### CDRH Programs:

- <u>OIVD's 510(k)</u>: Digital signatures are not accepted at this time for OIVD 510(k) submissions. In the future, the digital signature will be available in conjunction with the FDA ESG.
- <u>Radiological Health Reports and Correspondence</u>: Digital signatures are accepted and required when utilizing the FDA ESG to submit reports and correspondence. See note below regarding the FDA ESG. RadHealth Submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CDRH in lieu of using the FDA ESG.
- <u>eMDR MedWatch 3500A Form</u>: The eMDR program accepts digital signatures and utilizes the FDA ESG for transmission of the submission package. eMDR submissions may only be sent through the FDA ESG.
- <u>Medical Device ISO 13485</u>: Digital signatures are not accepted at this time for Medical Device ISO 13485 submissions. However, the CDRH program accepts submissions via the FDA ESG, as well as sending in by CD.
- <u>eCopies:</u> Digital signatures are not accepted at this time for eCopies submissions. eCopies submissions are accepted via CD and mailed to CDRH.

#### CBER Programs:

- <u>OBRR BLA/BLS Submissions</u>: Digital signatures are accepted and required for signing the necessary FDA OMB forms (Form 356h and Form 2567, when applicable). However, the CBER program does not accept submissions via the FDA ESG at this time.
- <u>ICSR Adverse Event Reporting</u>: Digital signatures are accepted and required when utilizing the FDA ESG for transmission of the submission package.

#### Continued on Next Page

### Packaging and Transmission Guidelines for Participating eSubmitter Programs (cont.)

#### **CTP Program:**

- <u>Tobacco Product Ingredient Listing, Health Data Submissions, and other CTP submission types not listed</u>: Digital signatures are accepted and required when utilizing the FDA ESG to submit ingredient listing and additional health data. Submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CTP in lieu of using the ESG.
- <u>Harmful and Potentially Harmful Constituents (HPHCs) Submissions:</u> Digital signatures are accepted and required when utilizing the FDA ESG to submit. HPHC submissions utilizing the eSubmitter software may still also be burned to CD and mailed to CTP in lieu of using the ESG.

#### CVM Program:

- <u>ONADE</u>: Digital signatures are accepted and required when utilizing the FDA ESG to submit eSubmitter electronic submissions to CVM.
- OSC DER: Digital signatures are accepted and required when utilizing the FDA ESG to submit eSubmitter electronic submissions to CVM.

Note regarding FDA Electronic Submission Gateway: CDRH's Radiological Health submissions program, the eMDR program and the CTP utilize the FDA ESG, an agency-wide entry point for all electronic submissions. CDRH uses the ESG to receive all electronic Radiation Safety Product, Annual, Abbreviated and Supplemental Reports and Correspondence types, and eMDR Med-Watch 3500A forms. The ESG authenticates and validates electronic submissions and routes it to the appropriate Center. Please visit <a href="http://www.fda.gov/esg/">http://www.fda.gov/esg/</a> to register as a trading partner for an initial ESG test account.

### **User Support**

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

For CBER - OBRR regulatory questions, please contact: <u>CBER\_eSubmitter\_program@fda.hhs.gov</u> or your Consumer Safety Officer.

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

For CDRH - eCopies

For eCopy technical questions, please contact: <u>cdrhesub@fda.hhs.gov</u>. For eCopy regulatory questions, please contact: CDRH-eCopyinfo@fda.hhs.gov.

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

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

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

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

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