eSubmitter Quick Guide - Generic Drug Facility Self-Identification

The eSubmitter software enables the electronic submission of regulatory information to FDA. FDA is using eSubmitter to help generic drug companies perform electronic self-identification of facilities and sites involved in the development and manufacturing of generic drugs. Electronic self-identification is requested by all such facilities and sites, whether or not user fees payments are required and if the facilities and sites are identified or intended to be identified in an approved or pending generic drug submission. Self-identifiers can generate electronic SPL files using eSubmitter and submit their SPL files through FDA's ESG.

For more information about technical details for utilizing SPL files, eSubmitter, and Generic Drug User Fee Amendments please refer to the User Support and Reference page of this document.

Inside this guide:

= *Important Tip*

= *Important Warning*

eSubmitter Icon Directory:

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

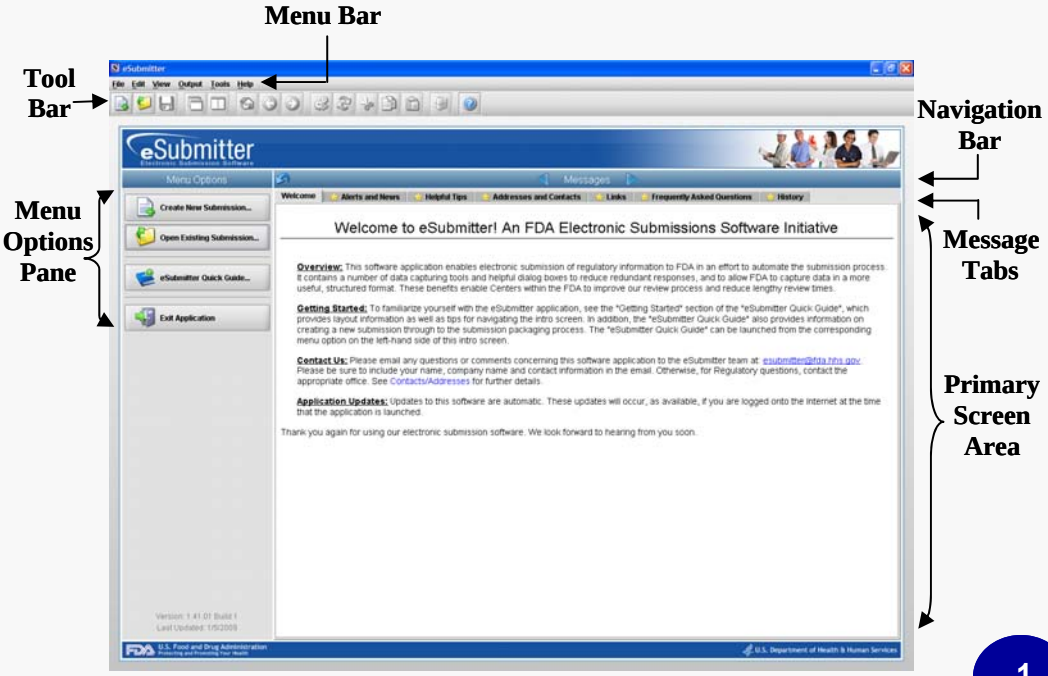
Access the Software

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

1. 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).
3. Click Next to continue the registration process. Or, click Register Later to register at another time. If you click Next, you will see a *Registration Dialog box.* 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.



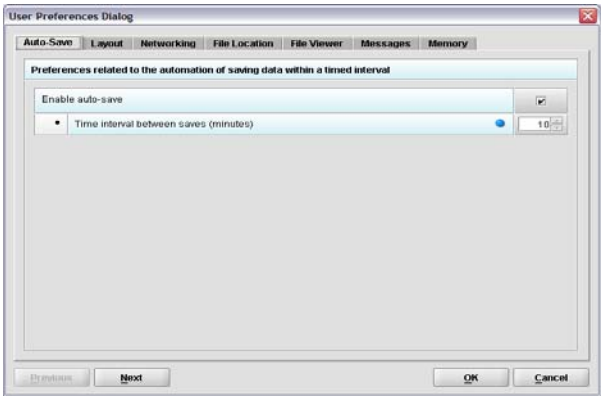
The contents of the *Welcome Screen* are described in the table below.

Function	Icon	Description
Create New Submission		Allows you to create a new submission entry. The *New Submission Data Dialog* box will appear. See section *Creating a New Submission* for more detailed information.
Open an Existing Submission		Allows you to open an existing submission. The *Open Submission Data Dialog* box will appear. See section *Opening an Existing Submission* for more detailed information.
eSubmitter Quick Guide		Launches the eSubmitter Quick Guide. If the Quick Guide does not contain the information you are searching for, see the full length eSubmitter User Manual (http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM266902.pdf).
Exit Application		Closes the eSubmitter application.
Help Topics		Displays the *Help Menu*, which provides instructional information and support for utilizing the eSubmitter application.
Forward Navigation Arrow		This arrow allows you to move forward through the **Message Tabs**.
Backward Navigation Arrow		This arrow allows you to move backwards through the **Message Tabs**.
Collapse/Expand Arrows		Allows you to collapse and expand the **Menu Options** portion of the *Welcome Screen*.
Notification Stars		The yellow stars are intended to notify users when new messages are available. The star appears next to the message tab header with new unread messages.
Category Filter		Allows you to filter the message information to display only generic information or those messages pertaining to a particular program. eSubmitter will remember the selected filter option upon closing and reopening the application.
Mark as Read		This checkbox enables you to indicate which message tabs have been read. Mark this checkbox to remove the yellow star shown next to the tab header. Unmark this checkbox to make the yellow star on the applicable tab header reappear.

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**.

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)

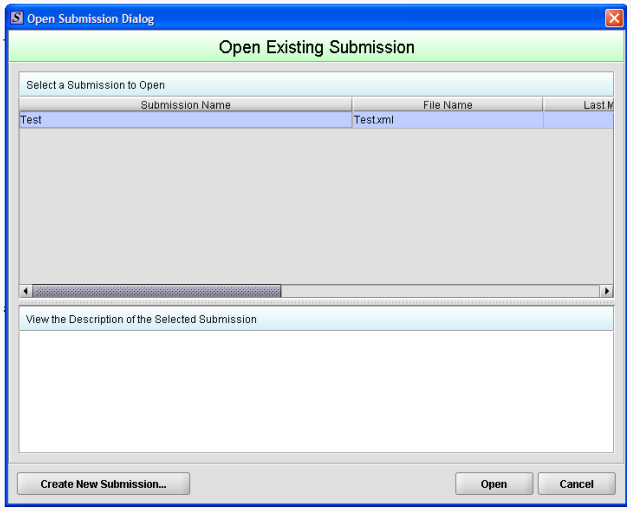
Messages: Allows you to indicate whether you will receive missing data message when leaving a screen.

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).

Open an 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*.)
2. 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*.
- **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 submission 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.

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

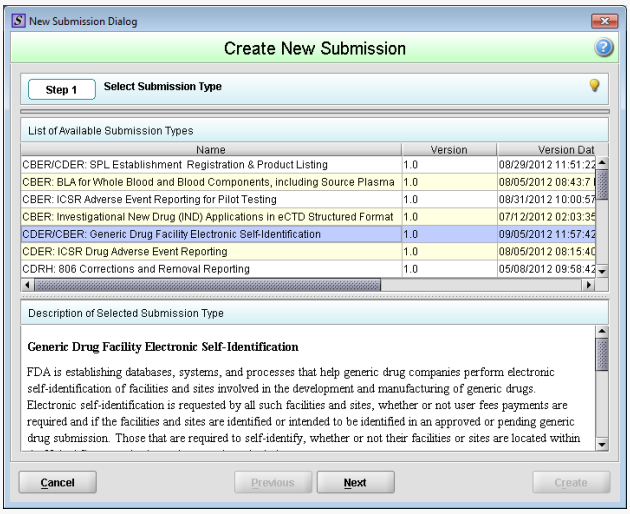
For more detailed instructions on setting your user preferences, see section 2.2 of the eSubmitter User Manual (http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM266902.pdf.

Create a New Generic Drug Facility Self-Identification Submission

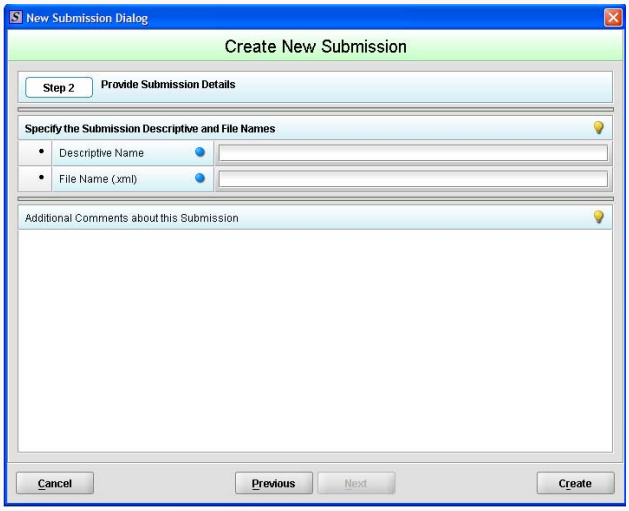
Follow the next steps to create a new submission from scratch:

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 ( ) on the **Tool Bar**. The *New Submission Dialog box* is displayed (as shown to the right).
3. In **Step 1. Select a Submission Type**, select **CDER/CBER: Generic Drug Facility Electronic Self-Identification .** When you click on the **Submission Type**, the bottom portion of the window displays information related to the corresponding submission type.
4. Once you have selected the **Submission Type**, click Next.

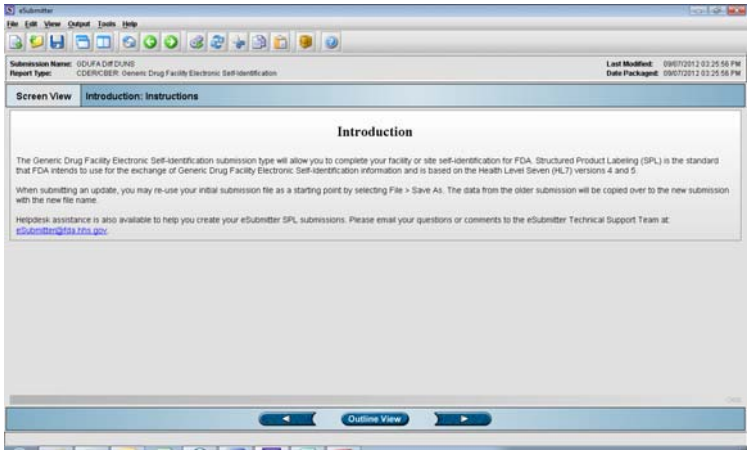


5. In **Step 2. Provide Submission Details**, complete the fields in the dialog box as follows:
   - **Descriptive Name** – Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (A required entry is indicated 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 Create



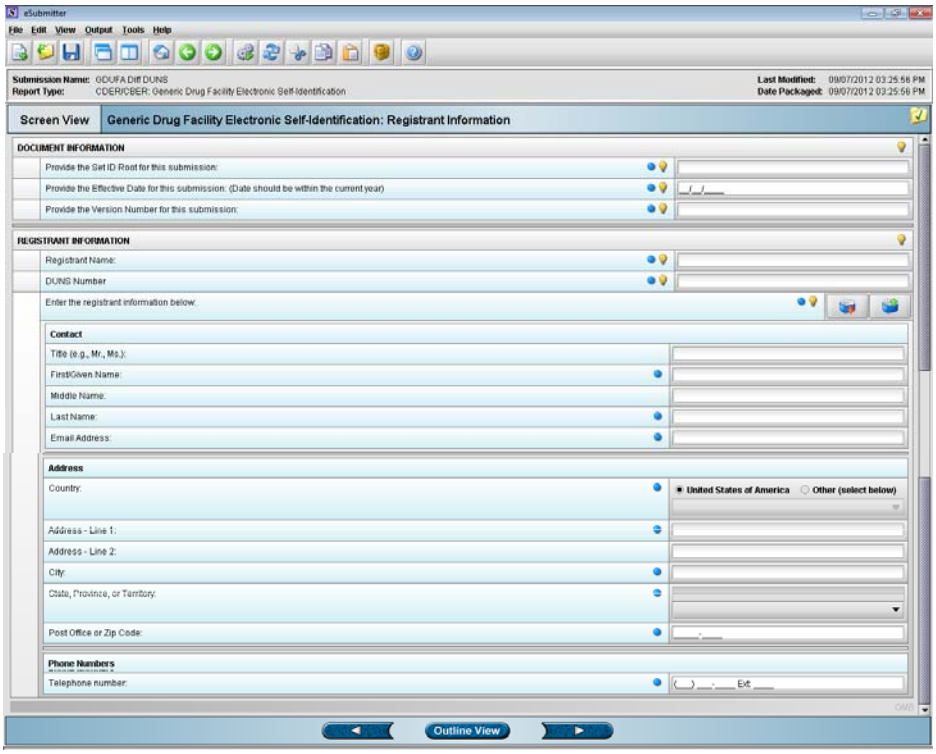
7. The **Overview** screen is displayed (as shown to the right). Click the green **Next** arrow to view **Instructions** screen.

Create a New Generic Drug Facility Self-Identification Submission - Continued



8. The **Instructions** screen is displayed (as shown to the right). Click the green **Next** arrow until you get to the **Registrant Information** screen.

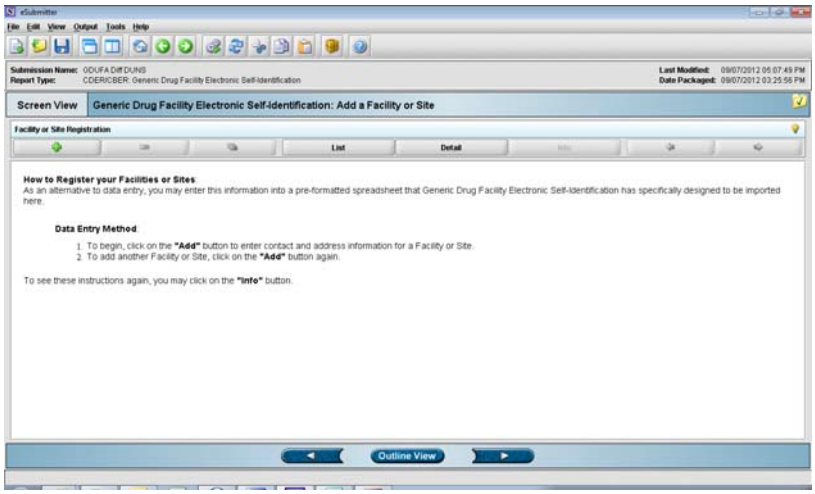
9. The **Registrant Information** screen appears (as shown below). Enter the following required registrant information data, *please note that required fields are indicated by the blue dots*:
    - Provide the Set ID Root for this submission
    - Provide the Version Number for this submission
    - Provide the Effective Date for this submission
    - Registrant Name
    - DUNS Number
    - Contact First/Given Name
    - Contact Last Name
    - Contact Email Address
    - Address Country
    - Address- Line 1
    - Address City
    - Address State, Province, or Territory
    - Address Post Office or Zip Code
    - Telephone Number



Note: To save the contact information for future use, select the Copy To Contact Book icon.

If the contact information already exists in the Contact Book, select the Copy From Contact Book icon to copy the data into the fields.

10. Click **Next** to view the **Add a Facility or Site** screen (as shown to the right). Click **Add New Item** (green plus icon) to enable the data entry screen.

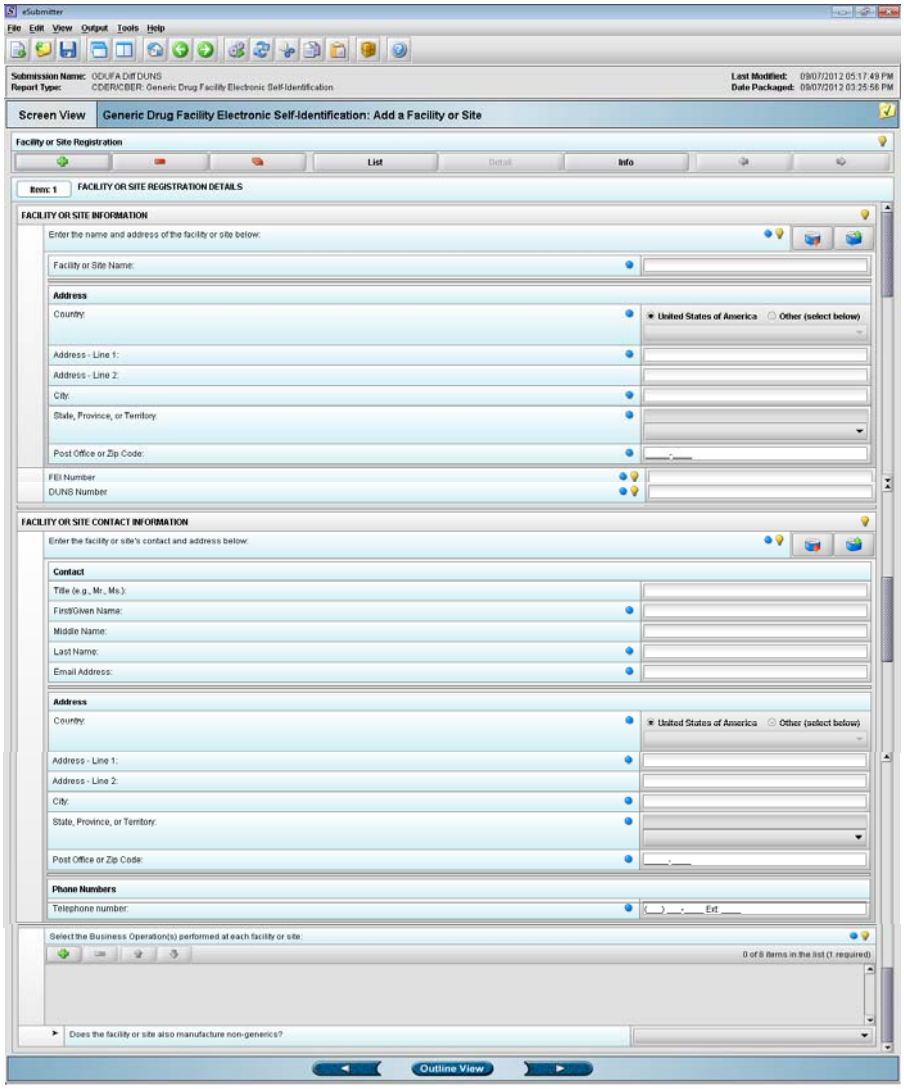


Create a New Generic Drug Facility Self-Identification Submission - Continued

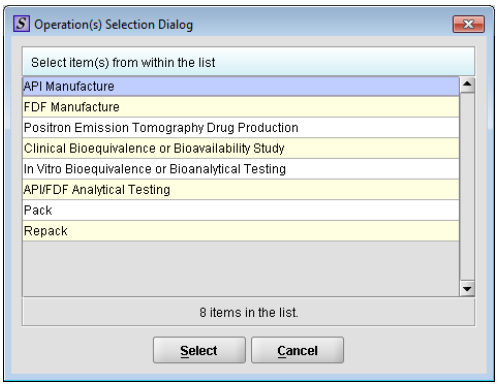
11. In the **Facility or Site Information** section, enter values into each of the following fields:
    - Facility or Site Name
    - Country
    - Address—Line 1
    - City
    - State, Province or Territory
    - Post Office or Zip Code
    - FEI Number
    - DUNS Number
    - First / Given Name
    - Last Name
    - Email Address

12. In the **Facility or Site Contact Information** section, enter values into each of the following fields:
    - First / Given Name
    - Last Name
    - Email Address
    - Country
    - Address –Line 1
    - City
    - State, Province or Territory
    - Post office or Zip Code
    - Telephone Number

13. Click **Add Item** (green plus icon) to select the **Type of Operation(s) Performed by Your Facility or Site**. The **Operation(s) Selection Dialog** box will be displayed (as shown below).



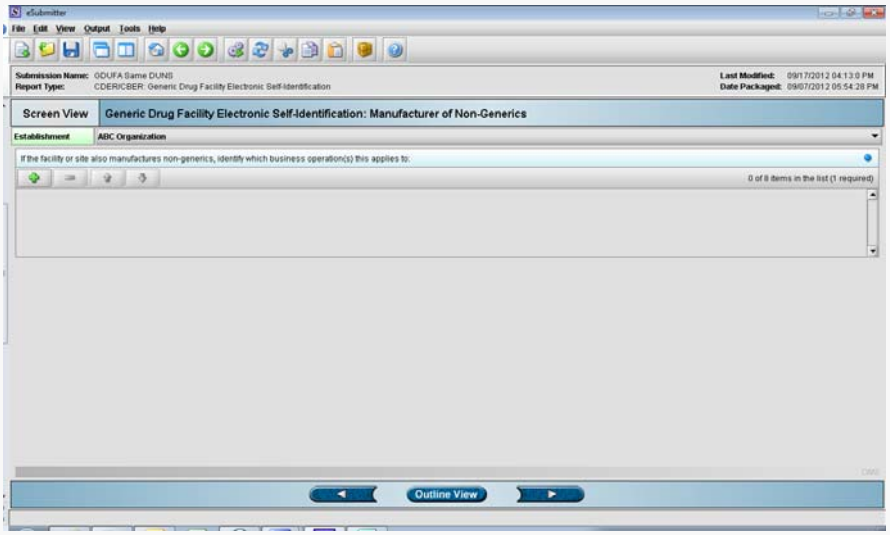
14. Select all business operation(s) that apply and click **Select.**



15. Select a response to '**Does the facility or site also manufacture non-generics?**' (as shown above).
16. If the user selects '**Yes**', the **Manufacturer of Non-Generics** screen will become enabled. If the user selects '**No**', proceed to step 18.

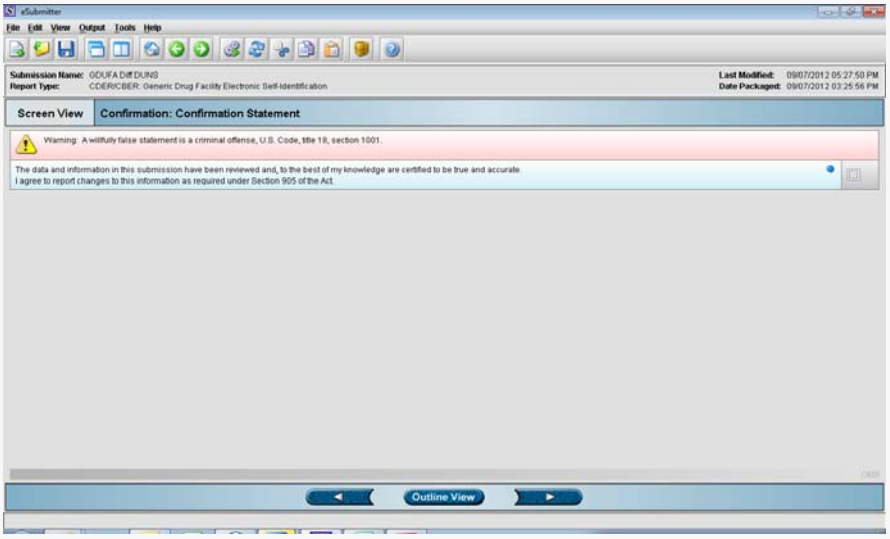
If more than one facility or site exists, click **Add New Item** (green plus icon) to add additional entries.

17. On the **Manufacturer of Non-Generics** screen, Click **Add Item** (green plus icon) to select the **Type of Operation(s) Performed by Your Facility or Site**.



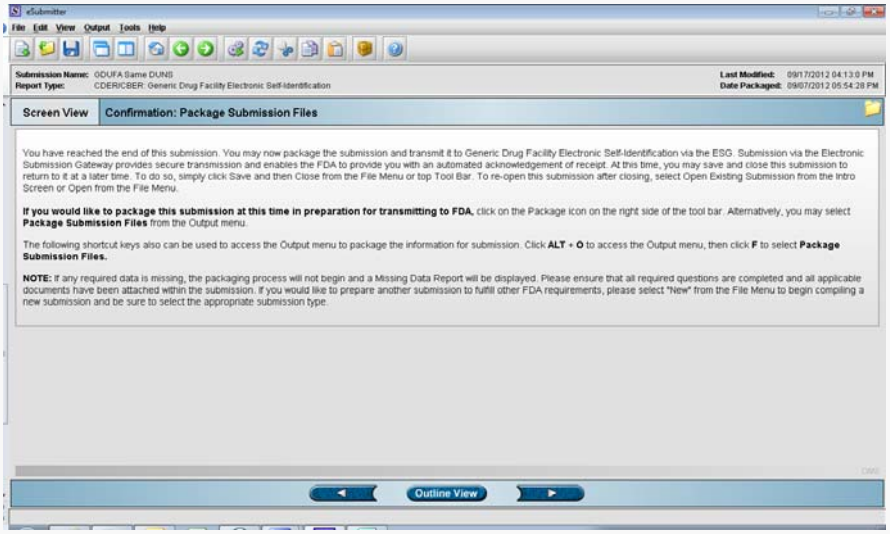
18. Select the appropriate response(s) to the question '**If the facility or site also manufactures non-generics, identify which business operation(s) this applies to**'.

19. Click **Next.** The **Confirmation Statement** screen is displayed (as shown to the right).



20. Agree to the statement by checking the box and click **Next**. Note: Agreement to the statement is needed in order to continue.

21. The **Package Submission Files** screen is displayed (as shown to the right). Follow the instructions on page 8 to package your submission.

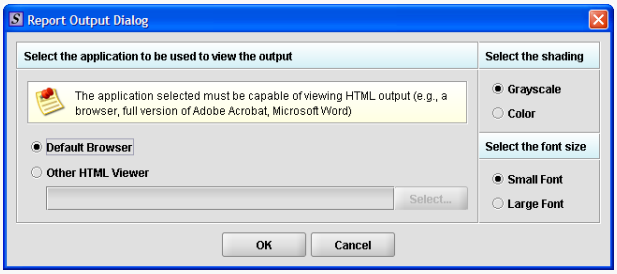


Check Completeness of Submission

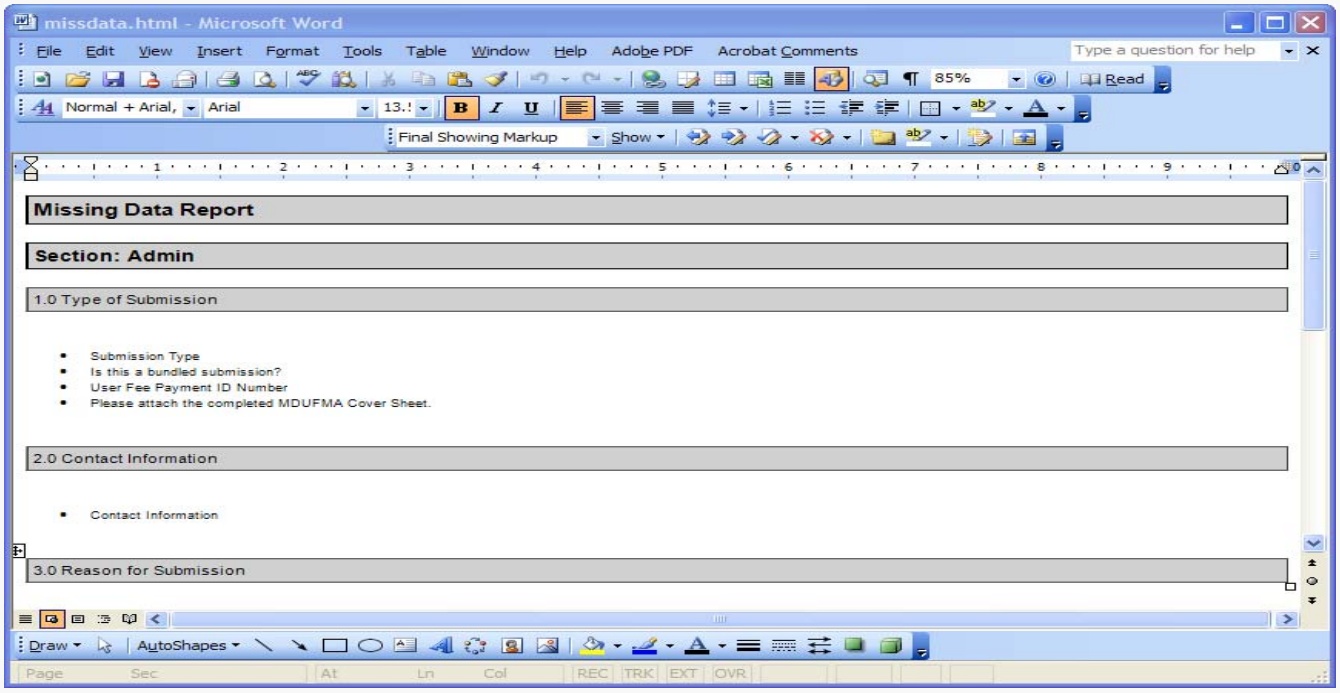
To check for completeness of a submission, you must identify if any data is missing from your report (and then enter the required data), and package the files for submission.

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.

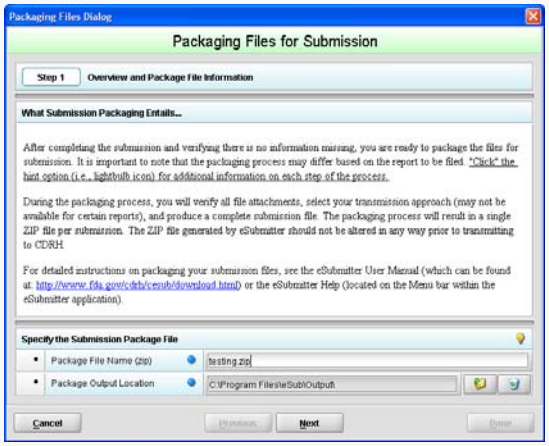


1. From the menu bar, click **Output > Missing Data Report**. The *Report Output Dialog box* is displayed (as shown to the right).
2. On this dialog box:
   - Select the desired application to view the output in HTML:
   - Click the option button: **Default Browser** or **Other HTML Viewer** (The default 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.
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 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 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.
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.***

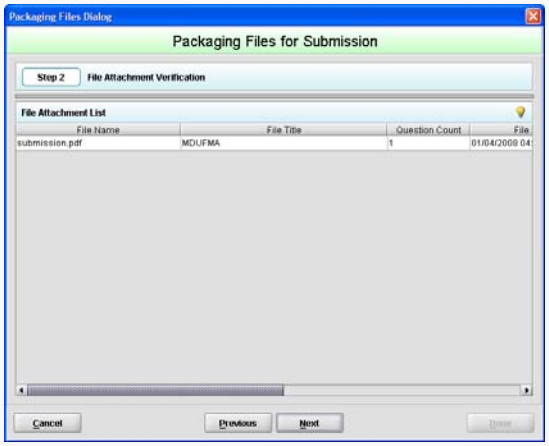


1. Click **Output > Package Files for Submission** from the menu bar.
2. If data is missing, a warning message will be displayed.
3. If the submission has all required data, the *Packaging Files Dialog box* is displayed (as shown to the right). Within the *Packaging Files Dialog box* you will be prompted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

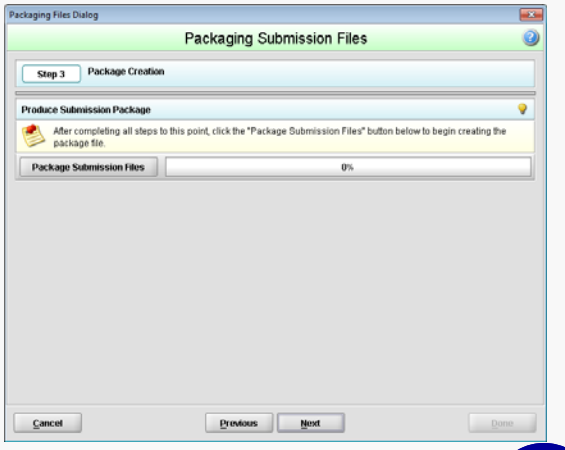
1. Specify the submission package file name.
   - The **Package File Name (.zip)** text box identifies the default zip file name for the submission. (eSubmitter automatically uses the submission name for the zip file.) Make a note of the name for the zip file.
2. Specify the submission output location.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



Step 2: File Attachment Verification

This section does not apply for GDUFA submissions. Click Next to proceed to *Step 3: Package Creation* and continue packaging the submission.

Step 3: Package Creation



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

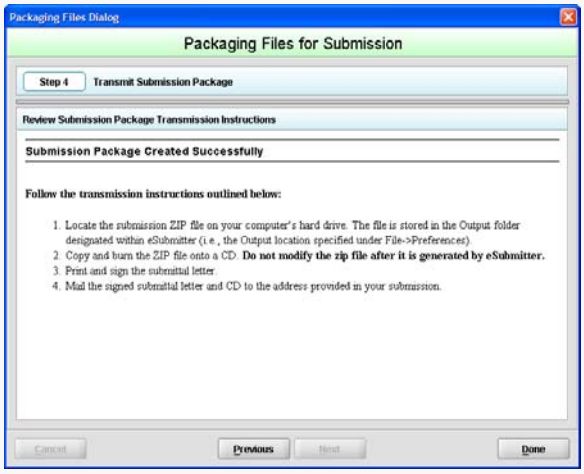
1. Click on Package Submission Files to initiate the packaging of the ZIP file.

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

2. Click Next to proceed to *Step 4: Transmit Submission Package* to view the transmission instructions related to your submission.

Step 4: Transmit Submission Package

This section provides confirmation that the submission files have been successfully packaged 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 to close the *Packaging Files Dialog box*.
   OR
   Click Previous to return to *Step 3: Package Creation*.

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 (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**.

If you still cannot locate the submission files, check within your User Preferences, by navigating to **File > Preferences > File Location**. The **Output Location** field will specify exactly where the submission files are located

4. Navigate to the appropriate location.
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. 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 June 2012, the following is acceptable for each participating program regarding digital signatures and the FDA Electronic Submissions Gateway. Please verify with the FDA program website that these guidelines have not changed. Program websites are accessible from the eSubmitter home page (http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm).

CDER Program:

- SPL Facility Self-Identification: Digital signatures are not accepted at this time for SPL facility self-identification submissions. The CDER program only accepts submissions via the FDA Electronic Submissions Gateway.

Package Submission and Transmit via ESG

Packaging the Submission in eSubmitter

Select the complete submission and click **Open**. The submission is displayed. Click Output > Packaging Submission Files. Alternatively, you can click on the **Package** icon. The **Packaging Files Dialog** is displayed.

1. Overview and Package File Information, verify that the Package File Name (zip) and Package Output Location fields are filled in. The Package File Name (zip) and Package Output Location fields are filled in. Click Next

2. **File Attachment Verification** is displayed. Note: The GDUFA submission does not include file attachments so this step will be blank. Click Next

3. **Package Creation** is displayed. Click Package Submission Files to package the submission. The Package Submission File displays a status of Complete. Click Next

4. **Transmit Submission Package** is displayed. See the instructions below for transmitting the packaged zip via the ESG. Click the Done Package Files Dialog is closed.

Transmitting the Submission via the FDA ESG

You must have an ESG account to execute the steps below.

1. Using the address provided by the FDA, access the FDA ESG Web Interface application. The **Login** page is displayed.

2. Enter the **User ID** and **Password** that was set up in the registration wizard. Click the **Login** button. The **My FDA submissions** page is displayed.

3. Click the **WebTrader** icon. The **WebTrader drop-down menu** is displayed.

4. Select the **Send document** menu item. The **Send document page** is displayed.

5. For CDER Submissions, select **CDER** from the Center drop-down box. The Center drop-down box is populated with CDER for the Center. For CBER Submissions, select **OC** from the Center drop-down box.

6. Click the **Browse** button associated with the Path textbox to select the submission. The submission file is displayed in the **Path** textbox.

7. For CDER Submissions, select the **GDUFA Facility Registration** submission type from the Submission type drop-down box. The GDUFA Facility Registration submission type is displayed in the Submission type drop-down box. For CBER Submissions, select the **SPL** submission type from the Submission type drop-down box.

8. Select a signing certificate by clicking the associated **Browse** button and select your appropriate certificate. The certificate is displayed in the **New file** textbox.

9. Click the **Send** button on the Send document page. The Enter password dialog box is displayed on top of the **Send document** page.

10. Enter the certificate password and click **OK** in the dialog box. The **Upload Progress dialog** box is displayed on the **Send document** page.

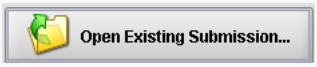
11. When the upload is complete (indicated by the display of Done), click the **Close** button in the **Upload Progress dialog** box. The submission is sent.

Closing and Reopening an Existing Submission

To Close a Submission:

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

To Reopen an Existing Submission:

- Click **File > Open** on the menu bar or 

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 

. The selected report is displayed.

To Exit the Application:

- To close eSubmitter, click 

on the *Menu Options Pane*.

User Support and Reference

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

For technical support or general inquiries, please contact:

- CBER: CBER_eSubmitter_program@fda.hhs.gov
- CDER: CDERefacility@fda.hhs.gov

The technical details for utilizing SPL files are available in the SPL Implementation Guide located on the FDA Data Standards Council Web site (http://www.fda.gov/oc/datacouncil/spl.html) .

For more eSubmitter information, please refer to the full length eSubmitter User Manual (http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM266902.pdf).

For more Generic Drug User Fee Amendments of 2012 (GDUFA) information, please refer to the GDUFA webpage (http://www.fda.gov/forindustry/userfees/genericdruguserfees/default.htm).

Appendix A: Business Operations Codes and Definitions

3.5. Business Operations:

3.5.1. Active Pharmaceutical Ingredients Manufacture (API) **Facilities (C82401):** Select option "API Manufacture" if the facility or site manufactures:

(A) Substance, or a mixture when the substance is unstable or cannot be transported on its own, intended to be used as a component of a drug and intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

(B) Substance intended for final crystallization, purification, or salt formation or any combination of those activities, to become the final active pharmaceutical ingredient as defined in paragraph (A) above.

3.5.2. Finished Dosage Forms Manufacture (FDF) Facilities (C101510): Select option "FDF Manufacture" if the facility or site manufactures:

(A) Drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) Drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) Any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of such a drug product as defined in paragraphs (A) or (B) above.

Entities that package drugs, other than those defined as repackagers (see below), are considered FDF manufacturers.

3.5.3. Positron Emission Tomography Drug Production (PET) Facilities (C91403): Select option "Positron Emission Tomography Site Drug Production" if the facility or site manufactures radioactive drugs administered to patients, which allow cameras and/or scanners to take images of internal body organs and tissues. This includes a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug, which:

(A) Exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) Includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

3.5.4. Clinical Bioequivalence or Bioavailability Study (BE) or (BA) Study Sites (C101511): This option corresponds with the statutory category "clinical research organizations." Select "Clinical Bioequivalence or Bioavailability Study" if the facility or site is a Clinical Research Organization (CRO) or is associated with a bioequivalence/ bioavailability study and engages in activities that include administering investigative drugs to human subjects for the purpose of demonstrating bioequivalence to a Reference Listed Drug. Associated activities include, but are not limited to, screening subjects, administering drugs to subjects, collection of biological specimens (e.g. plasma, serum, or urine) and safety monitoring, as specified in the study protocol.

3.5.5. In Vitro Bioequivalence or Bioanalytical Testing Sites (C101512): This option corresponds with the statutory category "a site in which a bioanalytical study is conducted." Select "In Vitro Bioequivalence or Bioanalytical Testing", if the facility or site conducts in vitro bioequivalence testing or measures concentrations of drug, drug metabolite, or other analytes as specified in the study protocol, in specimens collected during in vivo bioequivalence/bioavailability trials.

Business Operations Codes and Definitions

3.5.6. Active Pharmaceutical Ingredients / Finished Dosage Forms Manufacture Analytical Testing Sites (Contract API/FDF Analytical Testing) (C101509): Select option "API/FDF Analytical Testing" if the contract analytical testing facility or site is separate from the location of the processing facility for the API or the FDF and that is identified in the generic drug submission.

(A) Includes analytical testing sites that are responsible for testing one or more attributes or characteristics of the API including tests to verify purity, levels of impurities, particle size, and stability or;

(B) Includes analytical testing sites that are responsible for testing one or more attributes or characteristics of the FDF, including testing FDF in - process material, testing to qualify components used in the FDF, and testing to qualify components used in the FDF, and testing the stability of the FDF.

3.5.7. Contract Packaging Sites (Pack) (C84731): Select option "Pack" if the contract facility or site is separate from the location of the processing facility for the API or FDF and the site is owned or operated and identified in a generic drug submission, which include only packager sites that are named in an ANDA application. The facility or site is responsible for packaging the FDF into the primary container/closure system and/or labeling the primary container/closure system.

(A) Includes such activities as taking tablets from a large drum of tablets and packaging the tablets into individual bottles for retail sale and/or pharmacy use.

3.5.8. Contract Repackaging Sites (Repack) (C73606): Select option "Repack" if the contract facility or site is separate from the location of the processing facility for the API or FDF and the site is identified in a generic drug submission. The facility or site is responsible for removing the drug from a primary container/closure system and placing the contents into a different primary container/closure system.

(A) Includes facilities that remove a drug from a primary container/closure system and subdivide the contents into a different primary container/closure system (i.e., takes tablets out of a plastic bottle and packages the tablets into blister packaging).

3.6. Business Operations Qualifier: The Business Operations Qualifier is used in conjunction with the Business Operations types to indicate the facility or site also manufactures non-generic drugs. For each business operation type that is selected, **also** specify whether the facility or site also manufactures non-generic drugs.

3.6.1. Manufactures Non-Generics (C101886): Select option "Manufactures Non-Generics" business operations qualifier if the facility or site also manufactures non-generic drugs. For example, a facility or site that selects a business operation for API would use the business operations qualifier to specify whether they are also a facility or site that manufacturers non-generic drugs, and so on for each business operation that applies.