

eSubmitter Quick Guide: Packaging with Digital Signature

The packaging process outlined below is specific to packaging with a digital signature. This quick guide will instruct you on the basics for using the packaging wizard.

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 = Important Tip

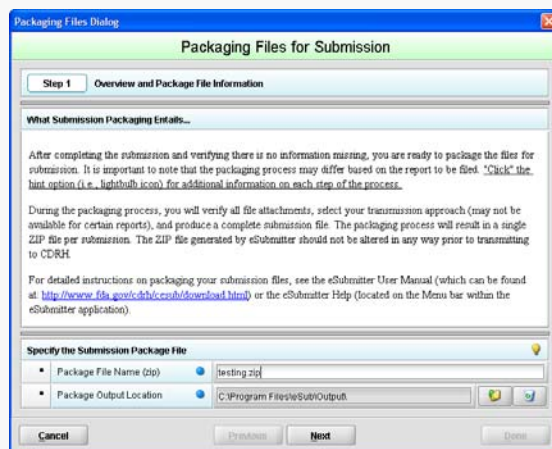
After completing the submission and verifying that there is no information missing, you are ready to package the files for submission. To proceed, the eSubmitter application should be open, and the finished submission displayed on your computer screen.

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.

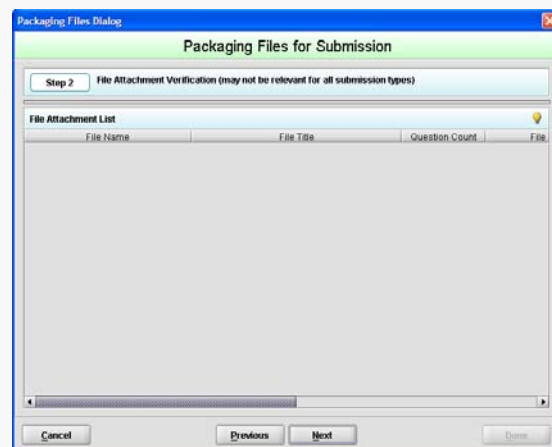
1. Specify the submission package file name.
 - The **Package File Name (.zip)** text box identifies the default zip file name for the submission. (eSubmitter automatically uses the submission name for the zip file.) Make a note of the name for the zip file.
2. Specify the submission output location.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

1. Click **Next** to proceed to **Step 3** and continue packaging the submission.
OR
Click **Previous** to go back to **Step 1**.
OR
Click **Cancel** and exit the *Package File Dialog* box.



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Step 3: Digital Signature, Package Creation

This section contains the final steps for reviewing the submission report, applying a digital signature and producing the submission package. At right is an example of what may appear in **Step 3**.






Review Submission Report

1. Click the **Review Submission Report...** button.
2. A PDF version of the report appears.
3. Ensure that your submission report is accurate.
4. Close window to return to Packaging Files Dialog.

Applying a Digital Signature

1. To attach your personal Adobe digital signature, click .
2. Locate filename of your Adobe digital signature and click .
3. Type in Digital Signature Password.


Produce Submission Package

1. Click on  to initiate the packaging of the zip file and verification of the digital signature and password.
-  An error message will appear if the digital signature/password is invalid.
2. A Certification Agreement Dialog pop-up may appear as seen at right.
3. Click  to proceed with packaging or  to return to the previous step. Once the submission has packaged successfully, the status bar will indicate that the packaging is complete.
4. Click  to proceed to **Step 4** to view the transmission instructions related to your submission.

Step 4: Transmit Submission Package

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

1. Read the instructions provided in Step 4 of the packaging wizard. These instructions will vary depending on the program for which you are submitting.
2. Click **Done** to close the *Packaging Files Dialog box*.
OR
Click **Previous** to return to **Step 3**.

 Please see <http://www.fda.gov/esg/> for Electronic Submissions Gateway (ESG) transmission instructions. Verify that the program for which you are submitting accepts submissions via the ESG. Otherwise, you will be required to mail in your submission on CD to the appropriate address.

User Support

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.

