
CVM ESUBMITTER USER GUIDE

CVM ESUBMITTER SIGNING PACKAGING

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I. INTRODUCTION

CVM requires that the firm (i.e., sponsor) provide, within their submission, the name and the digital signature of the individual who is authorized to make legal representation on behalf of the firm before the agency (i.e., the responsible official) (see 21 CFR §514.1(a)). Once the submission is received, the digital signature captured on the administrative cover sheet is validated against authorized stakeholders within the CVM Electronic Submission System (ESS).

II. OVERVIEW OF SIGNING OPTIONS

After completing the data entry of the submission in CVM eSubmitter you are ready to sign and package the files into a zip format for transmission to CVM. CVM has implemented two options regarding how Responsible Official signatures are applied by industry stakeholders to the Administrative Cover Sheet.

A. Option 1 – Sign During Packaging

Responsible Official digitally signs the submission within eSubmitter during the submission packaging step.

During the submission packing step, the responsible official provides their digital signature and eSubmitter generates a signed Administrative Cover Sheet and automatically includes it within the submission package. This approach requires the responsible official perform the packaging step.

Note: This is the original approach that has been in place since the release of CVM eSubmitter.

B. Option 2 – Externally Sign

Responsible Official digitally signs the Administrative Cover Sheet externally from eSubmitter and attaches it during the submission packaging step.

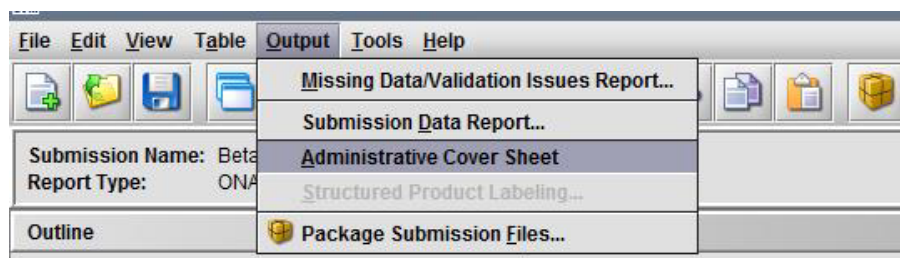
The Administrative Cover Sheet is output from eSubmitter and provided to the responsible official to digitally sign externally from the eSubmitter application. Once signed, the cover sheet is attached during the eSubmitter packaging step. Using this approach, the responsible official does not have to be present during the submission packaging process.

The firm contact information and key identifying details related to the submission must be available within the submission prior to outputting the cover sheet for external signing, and the key information, as captured at the time of the output, must remain unchanged. Otherwise, the cover sheet will need to be output and signed again, or it will be rejected during the packaging step.

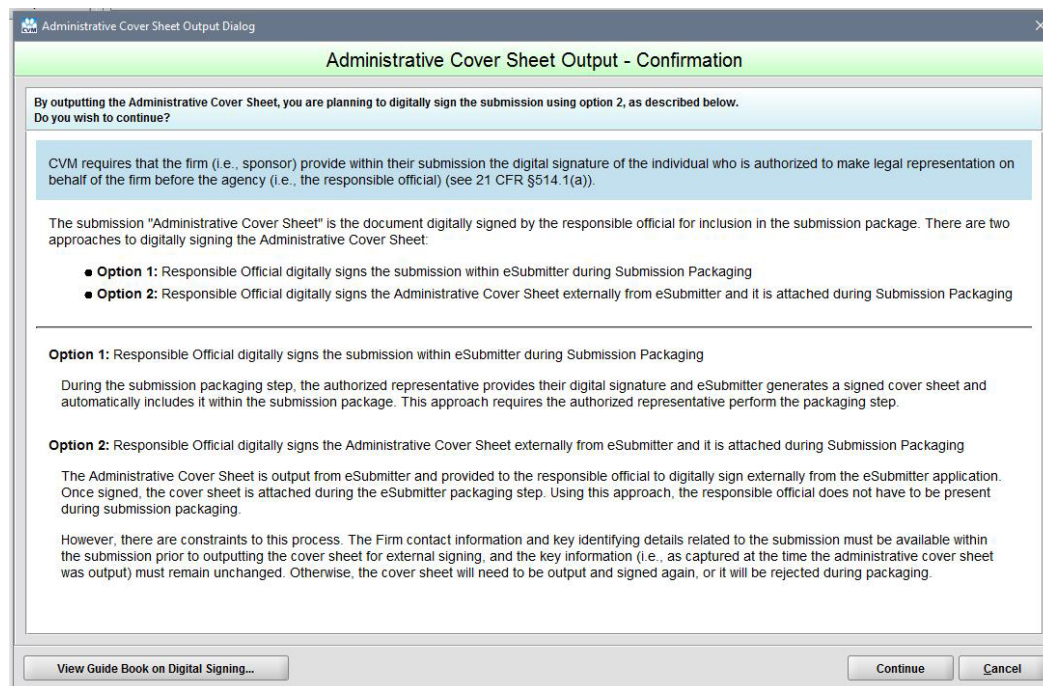
III. CREATING THE ADMINISTRATIVE COVER SHEET

A. Output Menu

To generate an Administrative Cover Sheet, access the “Output” option from the menu bar and select “Administrative Cover Sheet”.



A confirmation dialog box will be presented that describes the two options for applying digital signatures to eSubmitter submissions. Select “Continue” to generate the Administrative Cover Sheet.



B. Required Data Elements

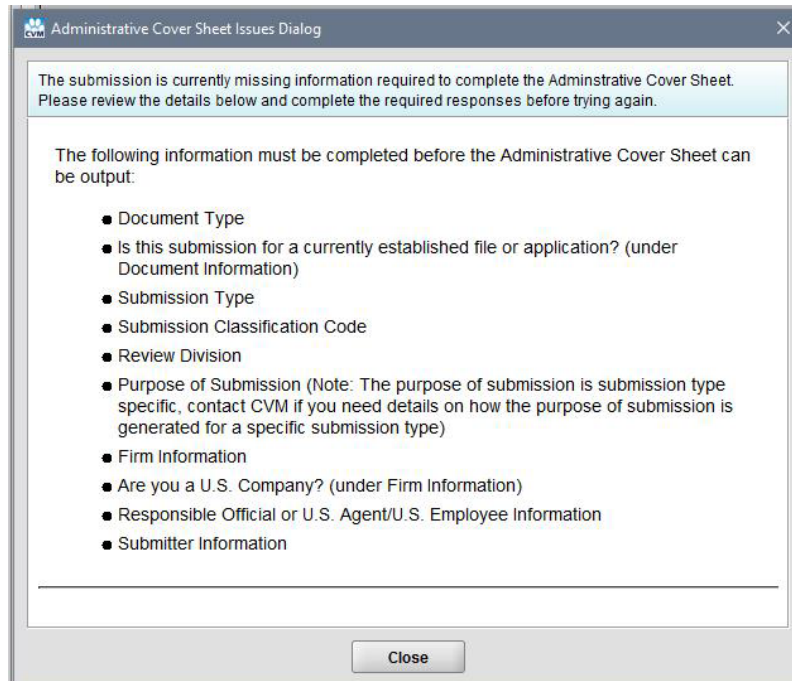
There are critical data elements that are required to generate a complete Administrative Cover Sheet. Depending on the type of submission you are creating, there are unique required data elements. Table 1 below indicates which data elements are required by submission type:

Table 1: Required Data Elements by Type of Submission

ONADE Required Elements	ONADE ABCT	ONADE Communication – Informal Communication	ONADE Communication – Early Response Letter
Document Type	Document Type	Type of Communication	Type of Communication
Currently Established File or Application	Currently Established File or Application	Document Type	Document Type
Document Number	Document Number	Document Number	Document Number
Submission Type	Submission Type	Firm Name	Firm Name
Submission Classification Code	Submission Classification Code	Review Division	Review Division
Review Division	Review Division	Responsible Official	Purpose of Submission
Purpose of Submission	Purpose of Submission	Purpose of Submission	-
Firm Information	File/Application Owner	-	-
Are you a U.S. Company	Responsible Official or U.S. Agent/U.S. Employee	-	-
Responsible Official or U.S. Agent/U.S. Employee	Submitter Information	-	-
Submitter Information	-	-	-

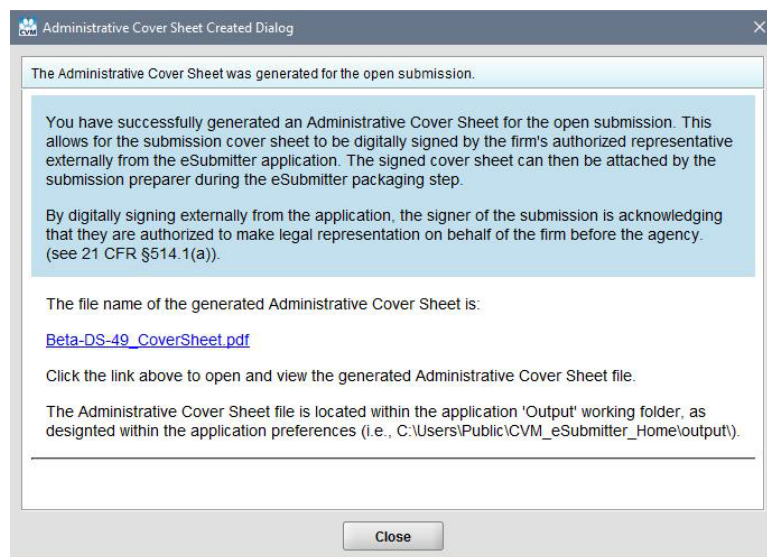
Note: The Purpose of Submission data element is created uniquely for most submissions. Contact CVM if you have questions about a specific submission type.

If any of *these* critical elements are missing, an error message will be generated informing you of the required elements that are missing.



C. File Location

Once the Administrative Cover Sheet is generated successfully, a dialog box will present the user with a confirmation as well as a link directly to the document. The file will always be saved to the location designated for the Output folder in the application preferences.



IV. PACKAGING

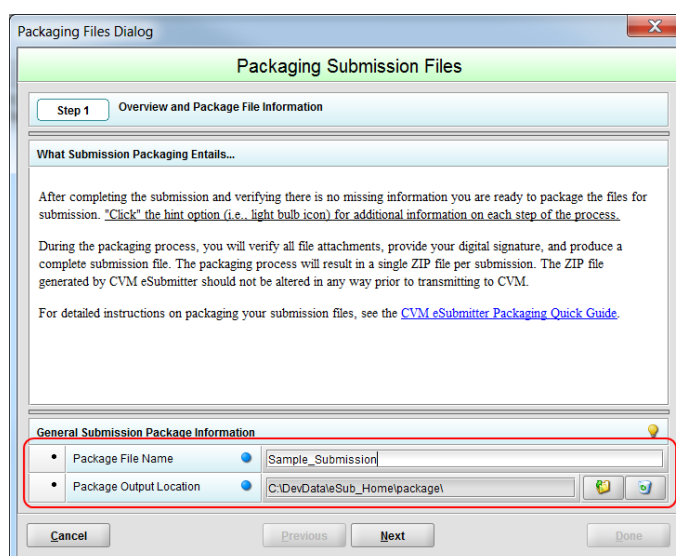
Select the Package Files for Submission option of the Output menu of the menu bar or click the Package button on the tool bar. If data is missing, a warning message will be displayed requiring you to correct any issues before proceeding. If the submission has all

the required data, the Packaging Files for Submission dialog is displayed that will lead you through a series of steps to complete the packaging process.

A. Step 1: Overview and Package File Information

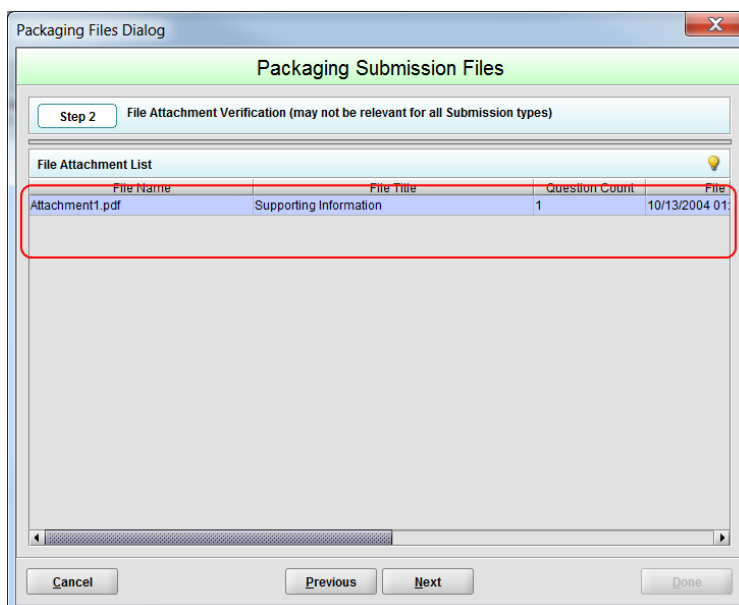
1. **Specify the Package File Name:** The Package File Name (.zip) text box identifies the name of the zip file to be generated for the submission. CVM eSubmitter automatically defaults the name of the zip file to match the name used for the submission data file.
2. **Specify the Package Output Location:** The Package Output Location identifies the file folder where the zip file is generated. To change the location, click the file folder icon and navigate to the new location.

Make note of the package file name and location so it will be easier to locate the package file when it comes time to transmit the file to CVM. Once completed, click the Next button to proceed to the file attachment verification step.



B. Step 2: File Attachment Verification

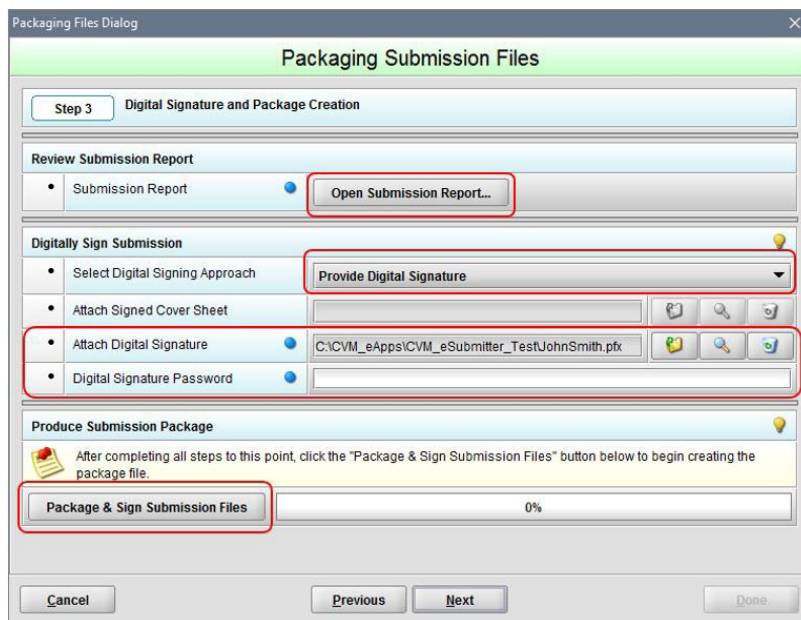
This screen lists all file attachments used in the submission. In addition, a check is performed to ensure all files contained within the submission are accessible for inclusion in the final submission package. Review all files listed and their file size. If all are correct, click the Next button to continue to the packaging step. Otherwise, click the Cancel button to exit the packaging process and return to the submission to correct any issues.



C. Step 3 Option 1: Signing During Packaging

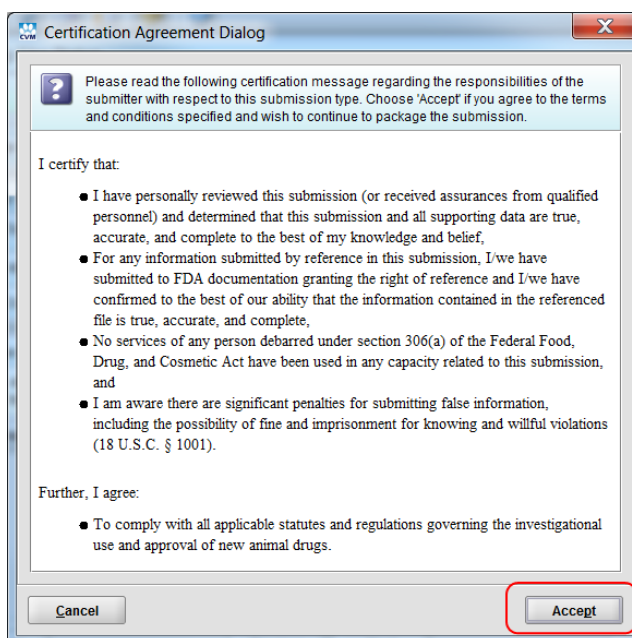
This section contains the steps for reviewing the submission report, applying a digital signature, and producing the submission package. Follow the instructions below:

1. **Review Submission Report:** Click the **Review Submission Report** button to open the submission report. Review and ensure the submission report is accurate and then close the report and return to the packaging dialog.
2. **Select Digital Signing Approach:** Select “Provide Digital Signature” from the drop-down list in the “Select Digital Signing Approach” question.
3. **Attach Digital Signature:** Click the folder button, locate the signature file using the file browser dialog, and select the appropriate digital signature file (.pfx). Once selected, CVM eSubmitter will maintain the file name and location for future packaging processes.
4. **Provide Digital Signature Password:** Type in the password for the digital signature attached. The entry of the password is required for each packaging attempt, but it will not be maintained by CVM eSubmitter for future packaging processes.
5. **Package and Sign Submission:** Click the **Package & Sign Submission Files** button to initiate the generation of the submission package (zip file).

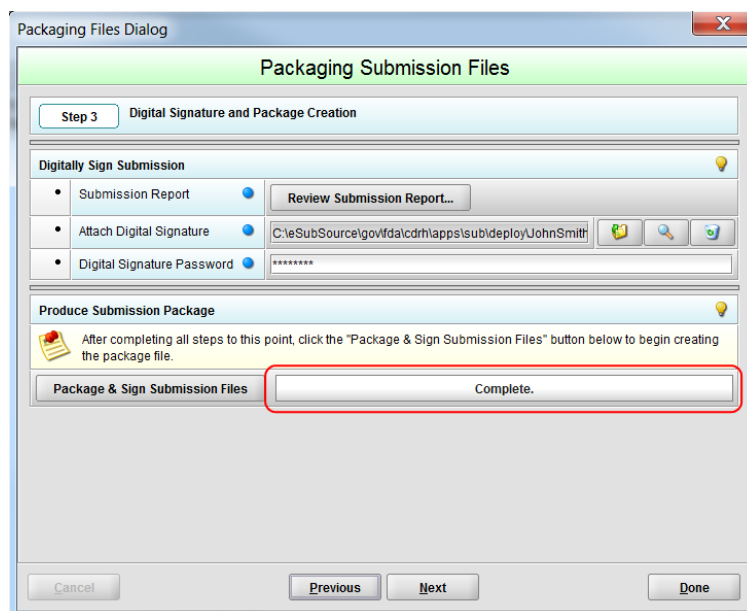


After initiating the package generation process, CVM eSubmitter will verify that the password for the digital signature is valid. An error message will be displayed if the password is invalid, and control will return to the packaging dialog to allow for the password to be corrected.

After successful verification of the password, a Certification Agreement dialog is displayed. You must click the **Accept** button for the certification agreement before CVM eSubmitter will generate the final submission package file.



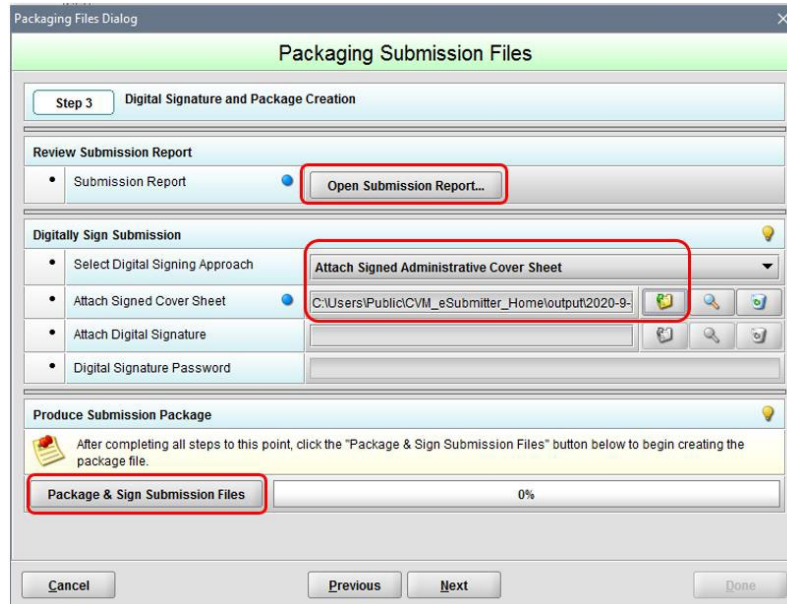
Once accepted, all files to be included within the submission package will be collected and the package file created. A "Complete" message is displayed if the package was created successfully. Otherwise, a "Failed" message is displayed. Click the **Next** button to continue to the transmission instructions step.



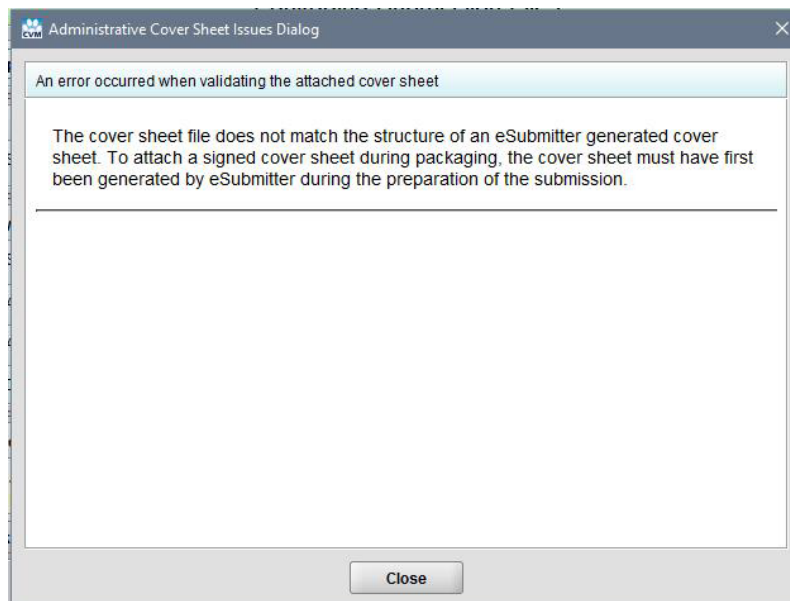
D. Step 3 Option 2: Attaching Signed Administrative Cover Sheet

If you have a signed Administrative Cover Sheet that you wish to attach, select "Attach Signed Administrative Cover Sheet" from the drop-down list in the "Select Digital Signing Approach" question.

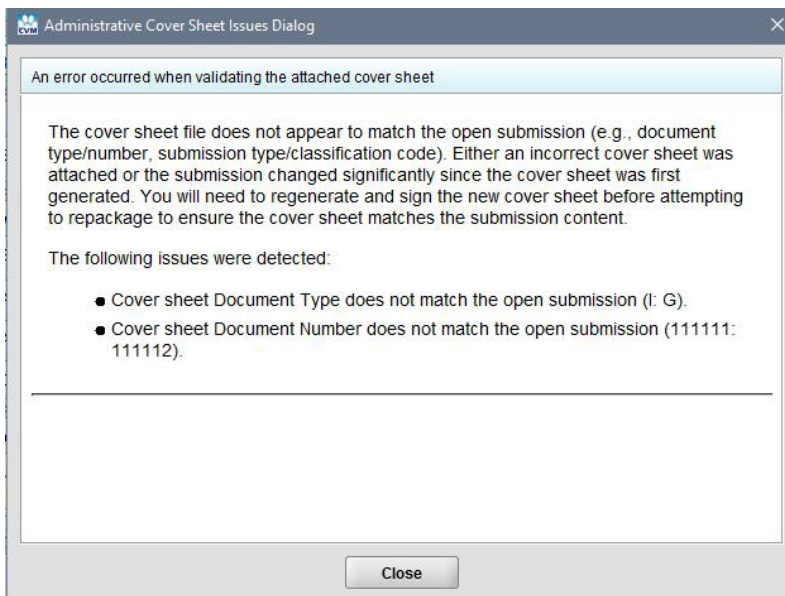
1. **Review Submission Report:** Click the **Review Submission Report** button to open the submission report. Review and ensure the submission report is accurate and then close the report and return to the packaging dialog.
2. **Select Digital Signing Approach:** Select "Attach Signed Administrative Cover Sheet" from the drop-down list in the "Select Digital Signing Approach" question.
3. **Attach Signed Cover Sheet:** Click the folder button, locate the signed Administrative Cover Sheet file using the file browser dialog, and select the appropriate file (.pdf).
4. **Package and Sign Submission:** Click the **Package & Sign Submission Files** button to initiate the generation of the submission package (zip file).



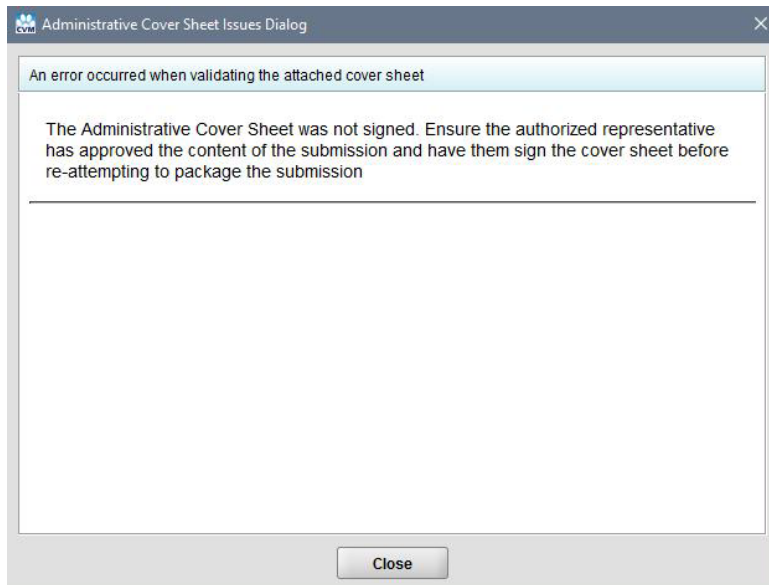
5. **Validation:** Once the **Package and Sign the Submission Files** button is selected, validation will be performed on the attached signed Administrative Cover Sheet to ensure that it is the correct file.
 - a. **Valid Cover Sheet:** eSubmitter validates that the attached file is an eSubmitter generated file. You will get the following error message if another PDF file is attached.



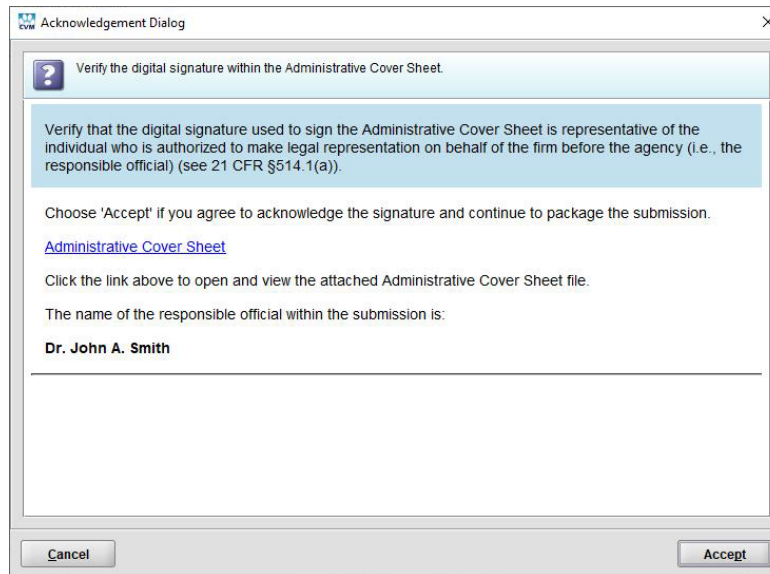
- b. **Submission Content:** If any of the submission critical content has been modified after the Administrative Cover Sheet was generated, the following error message will be displayed. The information inside the parenthesis will show you the cover sheet information, followed by current submission information. The corrective action for this error is to modify the submission or generate an updated Administrative Cover Sheet.



- c. **Signed:** eSubmitter will validate that a digital signature has been applied to the attached Administrative Cover Sheet. The corrective action for this error is to sign the file and reattach.

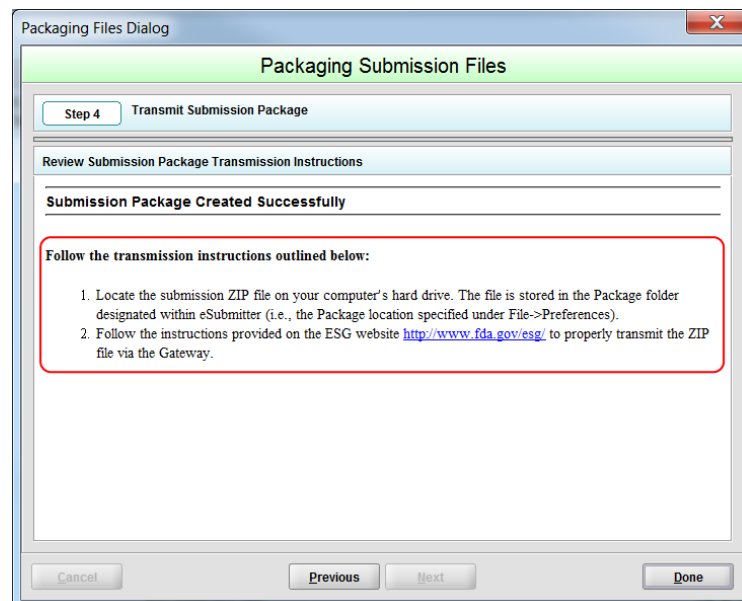


- d. **Completion:** Once all data elements pass validation, the following confirmation dialog box will be presented. This dialog box requests that the user confirm that the signature was applied by the responsible official designated within the submission.



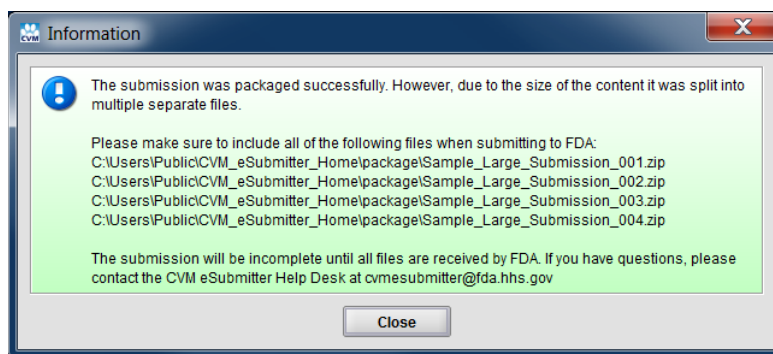
E. Step 4: Transmit Submission Package

This section contains either the final instructions for transmitting the submission package to CVM (packaging process successful), or an explanation of any issues detected during the process (packaging process failed). Click the Done button after reviewing the message to close the dialog.



F. Large Submission Packages

Very large submissions (i.e., over 1 GB) will be broken up into multiple smaller packaged ZIP files. The individual ZIP files will all use the same file name with an index number attached to the end. The standard manifest file included within each package contains a singular reference that links the files so that they can be processed together once all are received by CVM. The individual package files do not need to be sent or received in index order to be successfully processed.



V. RECOMMENDATIONS TO SPEED UP PACKAGING

There are three standard configurations for setting up eSubmitter within a sponsor environment (see the CVM eSubmitter Preferences Quick Guide for additional details):

- Option 1: User workstation install with each user working completely independent.
- Option 2: User workstation install with users sharing resources on a shared network drive (recommended).
- Option 3: Network install with users sharing the application and resources across a shared drive.

Submission size categories:

- Small: Less than 10 MBs (most of all submissions)
- Medium: 10 MBs to 30 MBs
- Large: 30 MBs to 100 MBs
- Very Large: 100 MBs to several GBs (where submissions over 1 GB are split into multiple submission parts)

The three items that have the largest impact on the time required to package a submission within eSubmitter are:

- Submission size: The cumulative size of all the attached files included within a submission.
- The location of the files included within a submission (i.e., local drive or network share).
- The location of the “packaging” folder where the submission package is generated (i.e., local drive or network share).

Below are tables of packaging sample test results based on common use and setup configurations:

Table 2: Both packaging folder and submission files located on the local drive

Submission Size	Location of Packaging Folder	Location of Submission Files	Packaging Time (hrs:min:sec)
8 MB	Local Drive	Local Drive	<00:00:01
20 MB	Local Drive	Local Drive	00:00:02
80 MB	Local Drive	Local Drive	00:00:05
620 MB	Local Drive	Local Drive	00:00:40
2500 MB (2.5 GB)	Local Drive	Local Drive	00:02:46

Table 3: Packaging folder on the local drive and submission files on a network share

Submission Size	Location of Packaging Folder	Location of Submission Files	Packaging Time (hrs:min:sec)
8 MB	Local Drive	Network Share	00:00:05
20 MB	Local Drive	Network Share	00:00:07
80 MB	Local Drive	Network Share	00:00:24
620 MB	Local Drive	Network Share	00:03:33
2500 MB (2.5 GB)	Local Drive	Network Share	00:20:31

Table 4: Both packaging folder and submission files located on a network share

Submission Size	Location of Packaging Folder	Location of Submission Files	Packaging Time (hrs:min:sec)
8 MB	Network Share	Network Share	00:13:44
20 MB	Network Share	Network Share	00:32:38
80 MB	Network Share	Network Share	02:15:10
620 MB	Network Share	Network Share	>17 hrs
2500 MB (2.5 GB)	Network Share	Network Share	>70 hrs

As can be seen by the sample testing results, the largest bottleneck in packaging is when the “package” folder is located on a network share. Thus, CVM’s recommendation is to set the packaging folder to a local drive and to manually copy the package file to a network share after the packaging process has completed.

VI. VERSION HISTORY

September 29, 2020 – Original version.

May 15, 2024 – Revised to update the document format and include specific validation requirements based on the type of submission being created.

November 15, 2024 – Revised to include recommendations to speed up the packaging process.