

CVM eSubmitter

Signing and Packaging Quick Guide

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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.

Option 1: 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.

Option 2: Responsible Official digitally signs the Administrative Cover Sheet externally from eSubmitter and attaches it during the submission packaging step

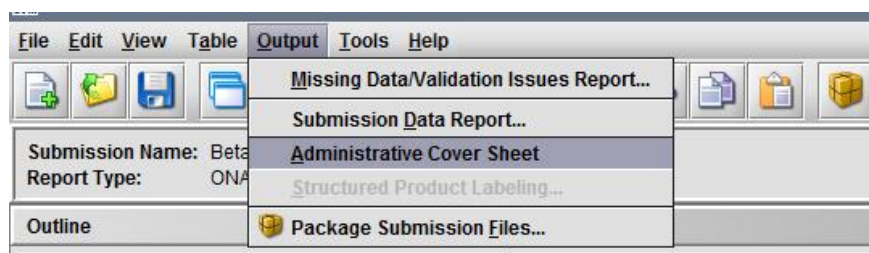
The Administrative Cover Sheet is output from eSubmitter and provided to the responsible official to digitally sign externally from the eSubmitter application. Once signed, the cover sheet is attached during the eSubmitter packaging step. Using this approach, the responsible official does not have to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

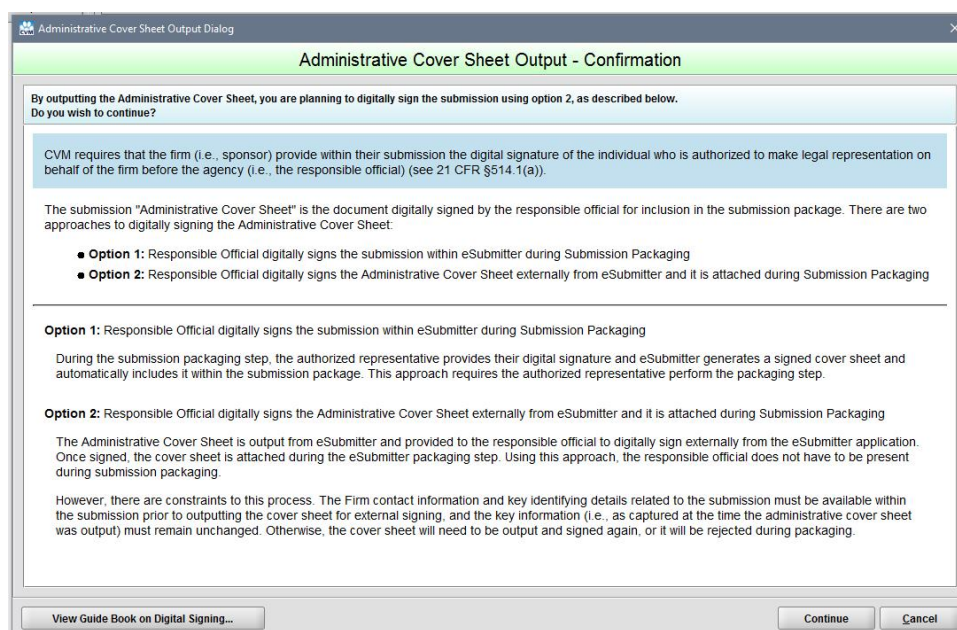
III. Creating the Administrative Cover Sheet

A. Output Menu

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



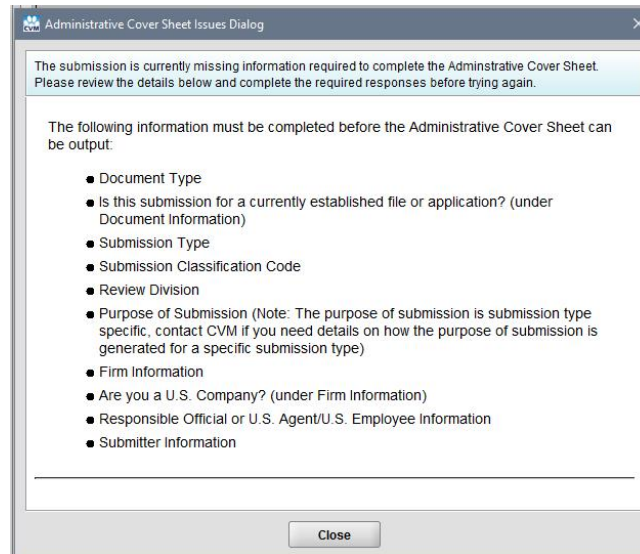
A confirmation dialog box will be presented that describes the two options for applying digital signatures to eSubmitter submissions. Select "Continue" to generate the Administrative Cover Sheet.



B. Required Data elements

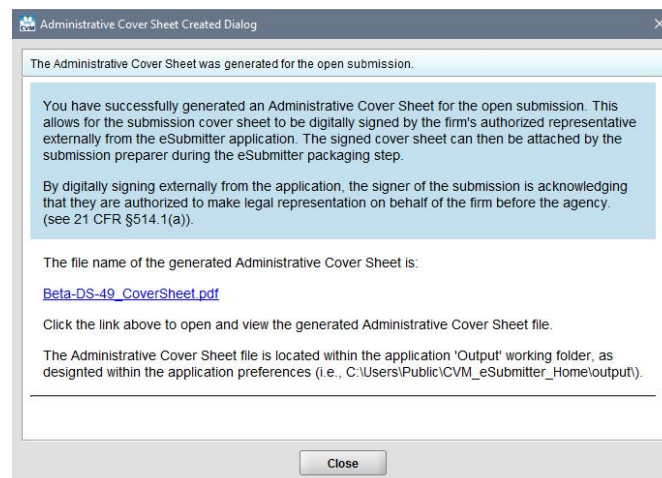
There are critical data elements that are required to generate a complete Administrative Cover Sheet. If any of these critical elements are missing, an error message will be generated informing you of the required elements that are missing.

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



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

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.

- **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.

Step 1: Overview and Package File Information screen

The screenshot shows the 'Packaging Files Dialog' window with the title 'Packaging Submission Files'. It has a tabbed interface with 'Step 1 Overview and Package File Information' selected. The main area contains text explaining the packaging process and a link to the 'CVM eSubmitter Packaging Quick Guide'. Below this is a section titled 'General Submission Package Information' with two fields: 'Package File Name' (containing 'Sample_Submission') and 'Package Output Location' (containing 'C:\DevData\Sub_Home\package\'). There are icons for file selection next to the output location field. At the bottom are 'Cancel', 'Previous', 'Next', and 'Done' buttons.

B. Step 2: File Attachment Verification

This section 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. 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.

Step 2: File Attachment Verification screen

The screenshot shows the 'Packaging Files Dialog' window with the title 'Packaging Submission Files'. It has a tabbed interface with 'Step 2 File Attachment Verification (may not be relevant for all Submission types)' selected. The main area contains a 'File Attachment List' table. The table has columns: 'File Name', 'File Title', 'Question Count', and 'File'. One row is visible: 'Attachment1.pdf', 'Supporting Information', '1', and '10/13/2004 01'. Below the table is a large empty area. At the bottom are 'Cancel', 'Previous', 'Next', and 'Done' buttons.

File Name	File Title	Question Count	File
Attachment1.pdf	Supporting Information	1	10/13/2004 01

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:

- **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.
- **Select Digital Signing Approach:** Select "Provide Digital Signature" from the drop-down list in the "Select Digital Signing Approach" question.
- **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.
- **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.
- **Package and Sign Submission:** Click the **Package & Sign Submission Files** button to initiate the generation of the submission package (zip file).

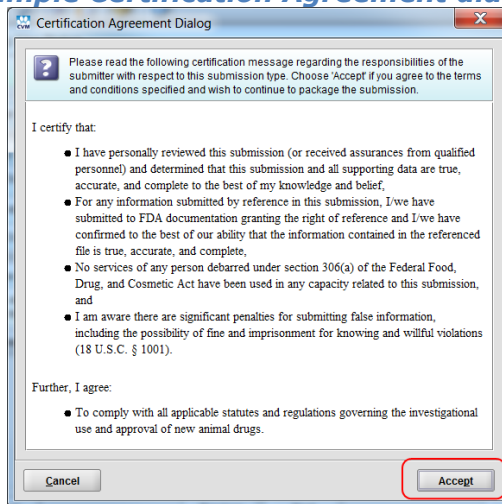
Step 3: Digital Signature and Package Creation screen

The screenshot shows the 'Packaging Files Dialog' window, specifically the 'Step 3: Digital Signature and Package Creation' tab. The window is titled 'Packaging Submission Files'. It contains several sections: 'Review Submission Report' with a button 'Open Submission Report...'; 'Digitally Sign Submission' with a dropdown menu set to 'Provide Digital Signature', and two input fields for 'Attach Digital Signature' (containing the file path 'C:\CVM_eApps\CVM_eSubmitter_Test\JohnSmith.pfx') and 'Digital Signature Password'; and 'Produce Submission Package' with a button 'Package & Sign Submission Files' and a progress bar at 0%. At the bottom are 'Cancel', 'Previous', 'Next', and 'Done' buttons. Red boxes highlight the 'Open Submission Report...' button, the 'Provide Digital Signature' dropdown, the file path input field, the password input field, and the 'Package & Sign Submission Files' button.

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.

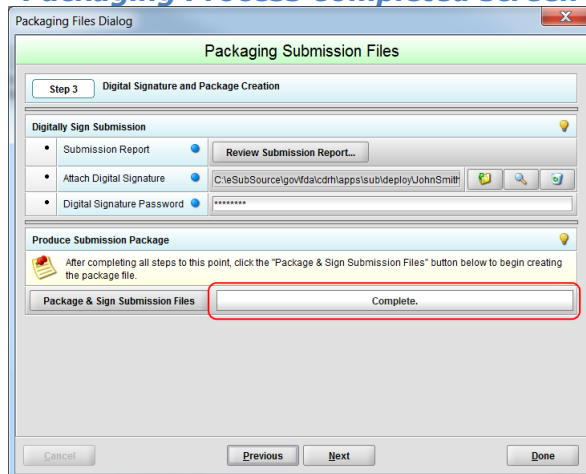
After successful verification of the password, a Certification Agreement dialog is displayed. You must click the **Accept** button for the certification agreement before CVM eSubmitter will generate the final submission package file.

Sample Certification Agreement dialog



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.

Packaging Process Completed screen

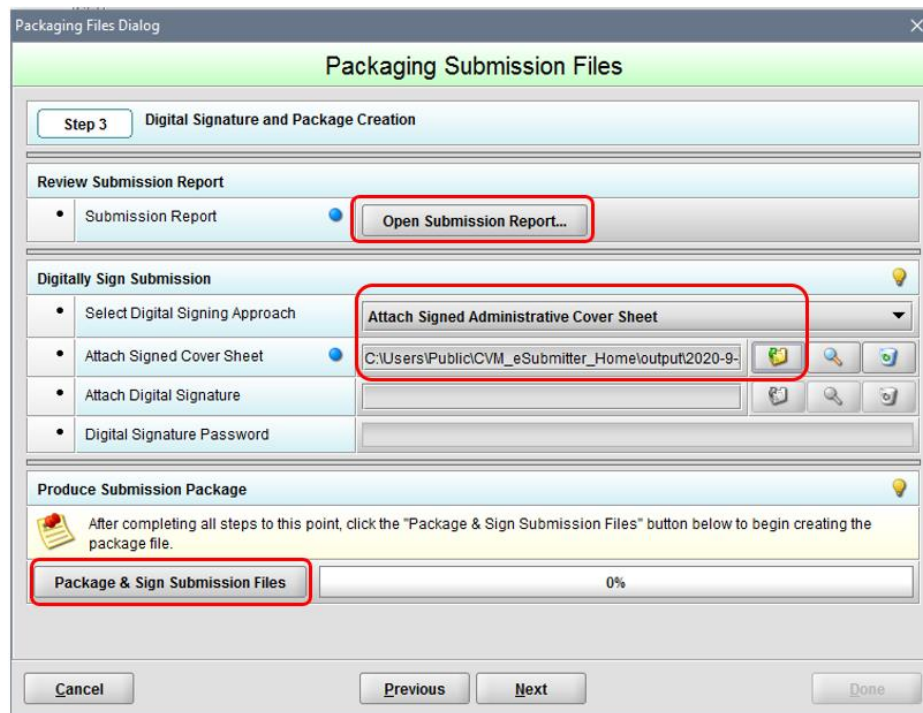


D. Step 3 Option 2: Attaching Signed Administrative Cover Sheet

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.

- **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.
- **Select Digital Signing Approach:** Select “Attach Signed Administrative Cover Sheet” from the drop-down list in the “Select Digital Signing Approach” question.

- **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).
- **Package and Sign Submission:** Click the **Package & Sign Submission Files** button to initiate the generation of the submission package (zip file).

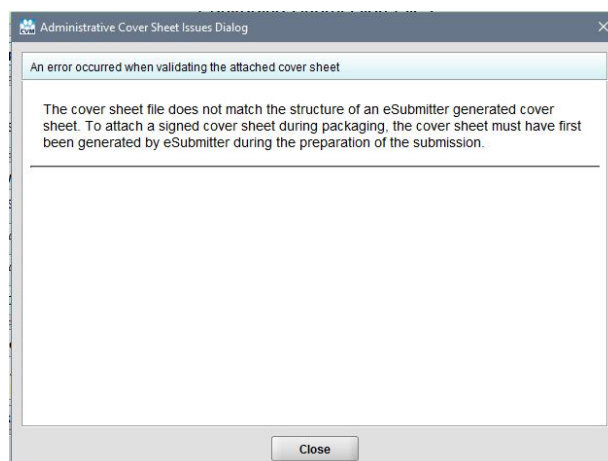


1. Validation

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.

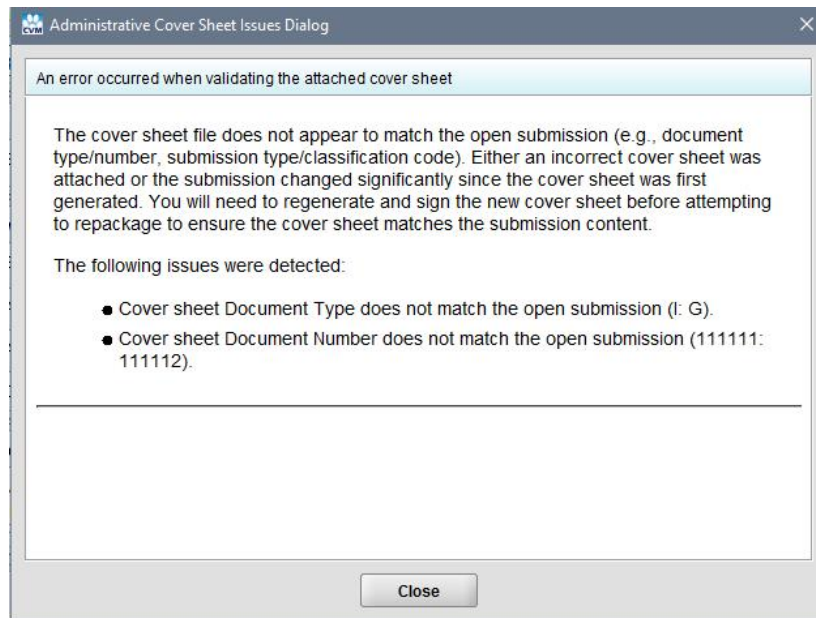
a. Valid Cover Sheet

eSubmitter validates that the attached file is an eSubmitter generated file. You will get the following error message if another PDF file is attached.



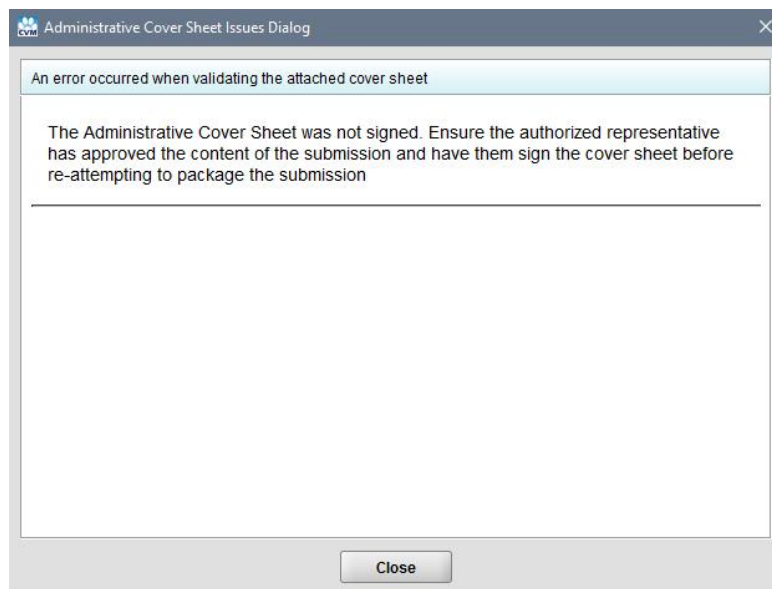
b. Submission Content

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.



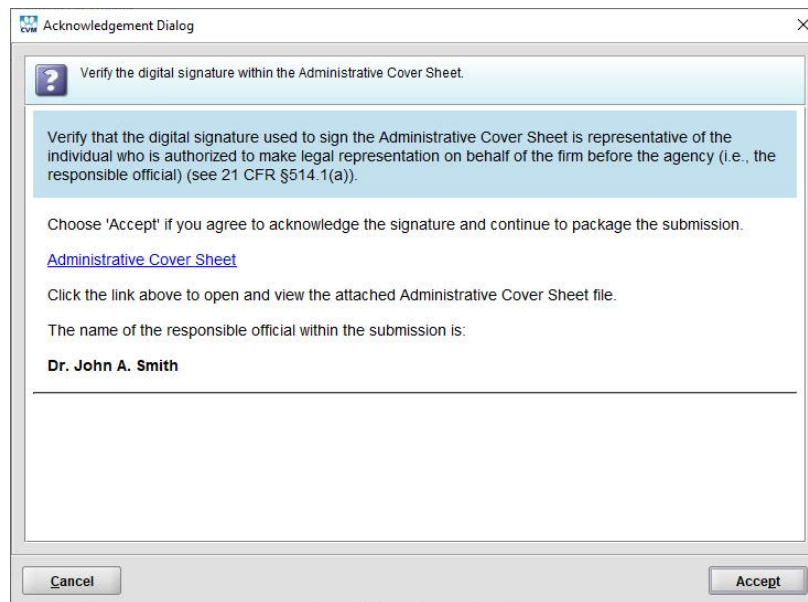
c. Signed

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

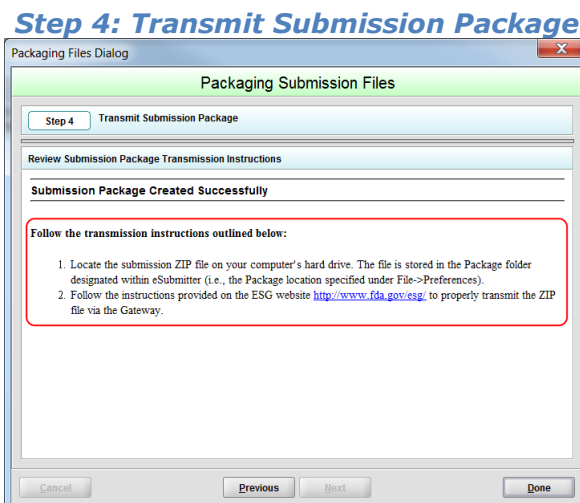
Once all data elements pass validation, the following confirmation dialog box will be presented. This dialog box requests that the user confirm that the signature was applied by the responsible official designated within the submission.



The submission is now ready for transmission to CVM.

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.

Sample Message Displayed after Packaging a Large Submission

