CVM eSubmitter

Animal Drug and Manufacturing (ADMS) Book Quick Guide

I.   Introduction

This guide outlines the functions associated with viewing and managing establishment information and supply chains in the Animal Drugs and Manufacturing System, or ADMS, database. The ADMS Establishments List is a tool used to manage the overall information on each establishment. There is a separate ADMS Supply Chain List, which is used to designate

the role of each establishment. Reusing data makes building a submission more efficient, as well as ensuring data entry consistency across submissions.

II.   ADMS Establishments Book

For ADMS, an Establishment is considered any facility that performs one or more activities involved in the manufacture or testing of drug substances or drug products intended for veterinary use. This excludes routine reporting of excipient manufacturers or testers, except for novel or critical excipients. This also excludes routine reporting of manufacturing and testing associated with container closure system components or single-use equipment. Any facility with Drug Product quality oversight or release responsibility only should be reported.

A. Access from the Tools Menu

Direct access to the ADMS Establishment book is available at any time from the Tools option in the menu bar.
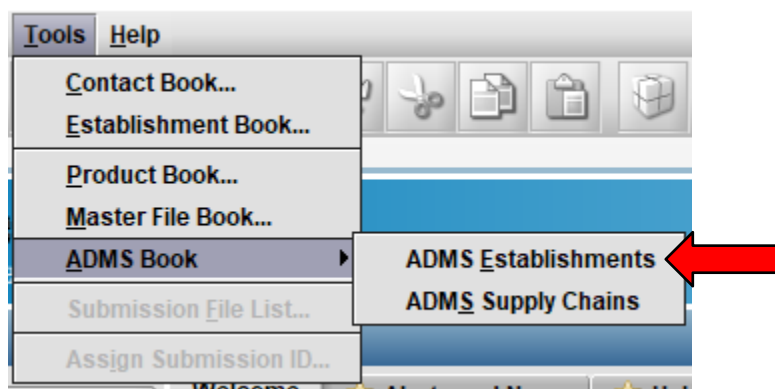
Accessing the establishment book from the Tools menu allows you to see all the currently entered establishments.

The Establishment List displays all the ADMS Establishments matching the search criteria, or all ADMS Establishments available when no search criteria are provided. The list contains the Establishment Name, DUNS, FEI, Country, State/Territory, and the date the information was last updated. The list title contains a count of the establishments currently included within the list. In addition, internal sponsor comments are displayed for the selected establishment.

The following options are available:

- View: Displays all details related to the selected establishment.
- Import: Allows for new/updated establishments to be inserted from an Excel spreadsheet
- New: Allows for new establishments to be added to the list.
- Edit: Allows for details on the selected establishment to be updated.
- Delete: Allows for the selected establishment to be permanently deleted from the list.

B. Search/Sort Criteria

The Search capability allows for searching across all ADMS Establishments contained within the ADMS Establishment List. The fields available for searching include Establishment Name, DUNS, and FEI. Specifically, the search locates all establishments matching all criteria provided.

The Establishment Name search allows for up to five keywords to be entered. Each keyword is separated by a space. The search matches all establishment names that contain words beginning with the keywords provided. The order of the keywords is not relevant to the search results. For example: providing 'co ab' as the search text would match 'ABC Company'.

The DUNS and FEI searches are based on locating all establishments that begin with the digits entered. For example: providing '123' as the search text for FEI would match an FEI of '123456789'.

When no search text is provided, all establishments are listed. A Clear option is provided to clear the search text and reset the establishment list.

The Sort capability controls the ordering of establishments within the list. The sort orders available include Establishment Name, DUNS, FEI and Country. Specifically, the establishment list will be reordered whenever a sort order is selected. The default sort order is Establishment Name. The sort order will reset to the default when the Clear option is selected

C. New Establishments

To add a new establishment, select the "New…" button at the bottom of the page. You are presented with a window with three tabs. The first tab, "Establishment"; this section collects information on the establishment name, reference identifiers (i.e., FEI and DUNS), address, phone numbers, and internal sponsor comments.

It is possible to have two establishments with the same name, however the DUNS number must be unique. It is important to make sure the FEI and DUNS numbers are accurate. The DUNS number is required for all establishments in a submission. While the FEI number is not required at the time of submission, the absence of this information may hinder the timeline for assessment of establishment information.

In addition, the following capabilities are provided:

- Copy from Establishment Book (Only Add Mode): Allows for establishment information to be selected and copied from the general eSubmitter Establishment Book.

- Check D&B D-U-N-S Number: Allows for the entered DUNS number to be checked against the ADMS Establishment List to determine if it is unique prior to the entering of the remaining information. If a unique number is used, the form will confirm the acceptability of the information. If the same number is found in the database, the check will notify the user that the establishment cannot be added.

- Establishment Comments: Adding internal comments allows you to capture additional information for overall management and identification of establishment information. This information is not transmitted to CVM.

D. Inspection Information

Add information about the GMP status of the establishment and date of last inspection on this tab.

Note: For information regarding the current inspectional status on a facility, see https://datadashboard.fda.gov/ora/cd/inspections.htm. If an inspection is scheduled, currently taking place, or completed but not yet classified you should select the status of the previous inspection.

The additional information section allows for the entry of any information about an inspection that has been scheduled, currently taking place, or completed but not yet classified.

E. Contact Details

This section collects information on the establishment contact name, address, and phone numbers.


In addition, the following capabilities are provided:

- Copy from Contact Book: Allows for contact information to be selected and copied from the general eSubmitter Contact Book.

- Copy from Establishment Address: Allows for the contact address to be copied from the establishment related details section.

F. Missing Information

Users may select OK at any point in the establishment entry process, even with incomplete information. A confirmation message will be displayed that provides details on which fields have not been filled out.
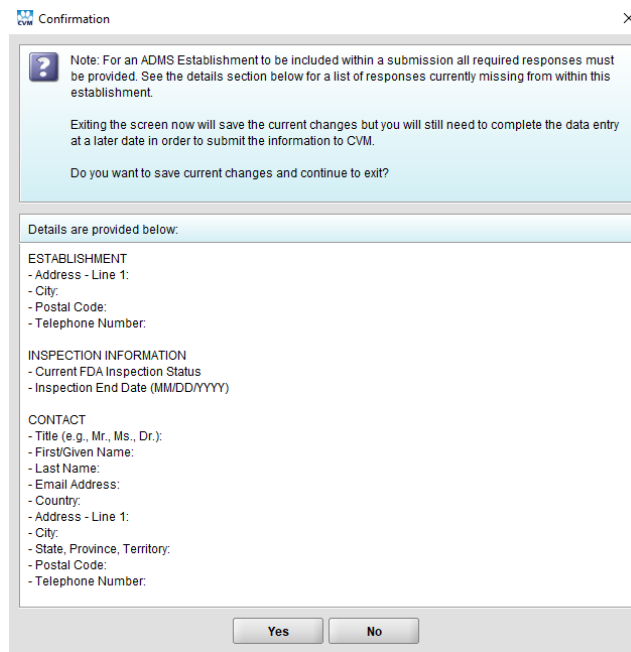
Note: For an ADMS Establishment to be included within a submission, all required responses must be provided.

G. Add Another Establishment

After completing an establishment entry and selecting OK, if you have additional establishments to add, select the Add Another Establishment button (Only Add Mode). Making this selection will clear the form to enable the entry of the next establishment.

H. Edit ADMS Establishment

Allows for details on the selected establishment to be updated. Establishment information can be edited by first selecting the desired establishment from the ADMS Establishment List, and then selecting Edit. Alternatively, you can double-click the establishment name in the list to open the same window. On this screen, the establishment information on each tab can be edited. To save any edits, simply select OK when finished.

I. Delete ADMS Establishment

To delete an establishment, select the desired establishment from the ADMS Establishment List, and select Delete at the bottom of the form. A warning message will appear to confirm the deletion, which after doing so, will remove the establishment from the list.
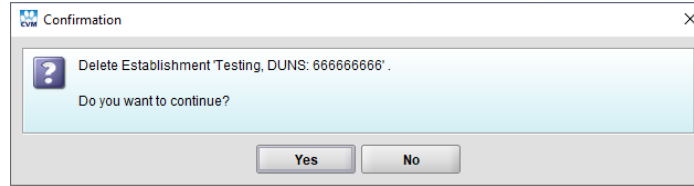
If an establishment is associated with a supply chain item, you will not be able to delete it without either redirecting the associated supply chain items to other establishments or deleting the supply chain items.
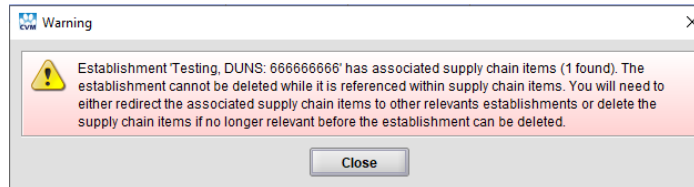
J. View ADMS Establishments Report
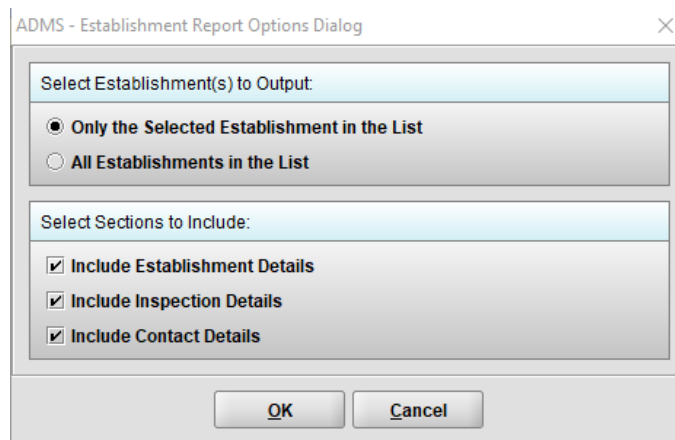
Users have the option of viewing the establishment report for a selected establishment, or for all establishments within the list. Select the View button after selecting the desired establishment. The dialog box which opens gives the option to select which establishments to output.

Only a single establishment or all establishments can be selected; multiple establishments cannot be selected using "Ctrl" or "Shift". After selecting which sections should be included in the report, the file will open in your default html viewer.

H. Import ADMS Establishments

Users have the option of importing establishments from an Excel spreadsheet using common copy and paste operations. A sample spreadsheet file for importing establishments has been provided within the "import" subfolder of the application folder. In addition, a link to the file has been provided within the hint located at the top of the establishment list dialog. Once selected, the Copy/Paste ADMS Establishment Import Wizard dialog will be displayed.
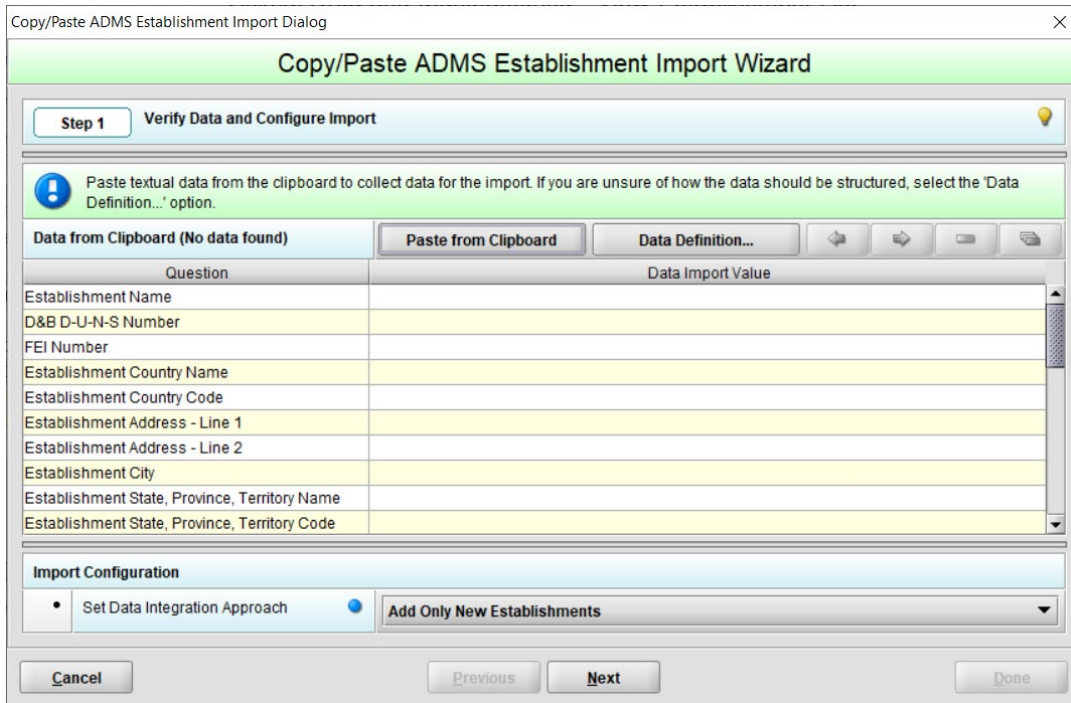
Prior to using the copy/paste wizard, establishment data must be copied from an appropriately structured Excel spreadsheet containing establishment information to import. To perform the copy, select the rows in the spreadsheet to be imported and initiate a copy of the data to the system clipboard using the CTRL+C keyboard short-cut, or the copy option from the Excel toolbar. Once establishment data has been copied, return to the ADMS Establishment Import Wizard dialog.
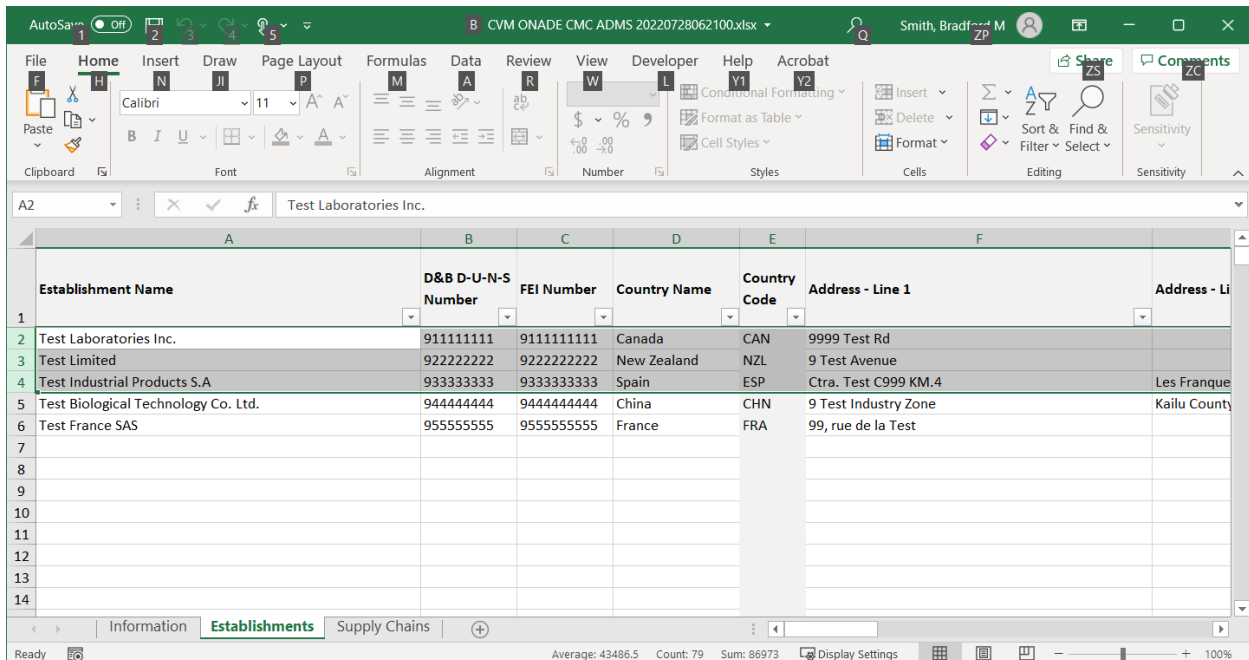
The following options are available from the Copy/Paste Import dialog, Step 1: Verify Data and Configure Import:

- Data Definition: Displays within the browser a table listing the data constraints that will be used to validate the establishment information as part of the import (e.g., maximum length checks, formatting constraints). The sample spreadsheet provided includes built-in logic to ensure appropriate coding has been followed (e.g., GENC country/state codes).
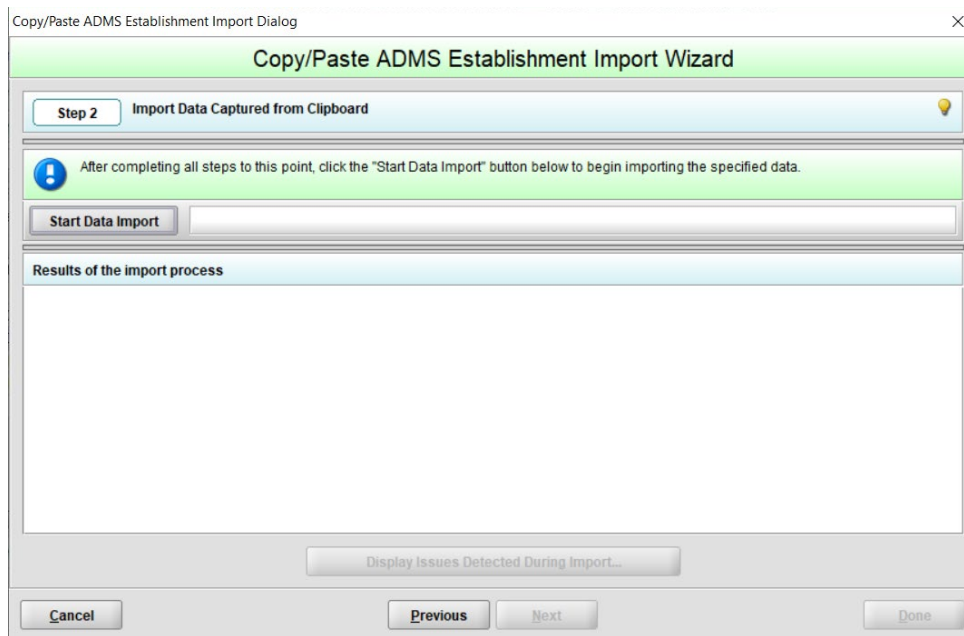
- Paste from Clipboard: Extracts the establishment information from the system clipboard and loads it into the dialog's data table. Once performed, a dialog will display identifying the number of rows pasted from the clipboard. The copy/paste process can be performed multiple times to collect data within the import dialog prior to performing the import operation.

  Note: the system clipboard only holds information from the latest paste performed within the Windows operating system, so make sure the copy from Excel is performed just before pasting into the eSubmitter wizard dialog.

- Data Pasted from the Clipboard: Table holding the contents of the paste. Only one establishment is shown at a time in a vertical orientation with a reference to the type of data in the first column (e.g., Establishment Name) and the data pasted in the second column.

- Previous Row and Next Row: Supports navigating between rows of establishments within the data table to support viewing/verification of the content to be imported, prior to the import operation.

- Delete Selected Row and Delete All Rows: Supports the removal of row(s) within the data table prior to the import operation.

- Data Integration Approach: Determines how the import operation will deal with duplicate data found within the contented to be imported and the data already existing within the ADMS establishment list.

  o Selecting "Add Only New Establishments" will ignore establishments within the content to be imported if the DUNS already exists within the ADMS establishment list.

  o Selecting "Add Only and Overwrite Existing Establishments" will overwrite establishments within the ADMS establishment list with the content to be imported when the DUNS matches.

- Next: This option moves to the next step in the import process, after data has been pasted from the clipboard and an integration approach has been selected.

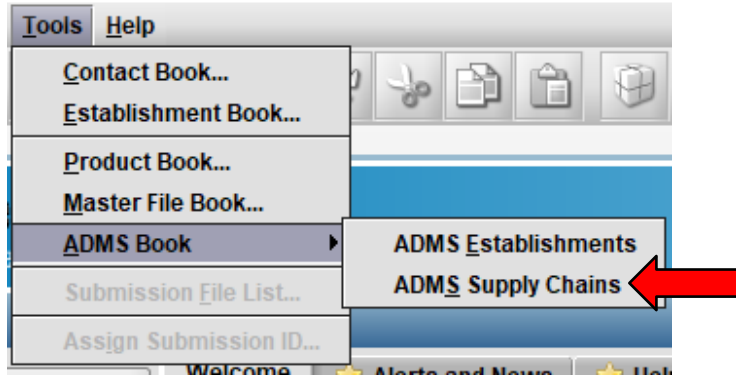- Cancel: This option cancels the import operation and closes the import dialog.

The following options are available from the Copy/Paste Import dialog, Step 2: Import Data Captured from Clipboard:

- Start Data Import: Selecting this option initiates the import of the establishment data. There are two types of results displayed after the import:
    o Data Imported Successfully with a count of the number of rows imported, or
    o Data Imported with Issues with a count of the number of issues found.

- Display Issues Detected During Import: Displays within the browser a table listing the issues detected. Each issue identifies the row of the data where the issue was encountered as well as a description of the issue.
    o Issues resulting in warnings mean that data was imported but it may have been modified to support the import (e.g., truncated because it was too long), and should be verified after the import.
    o Issues resulting in errors mean that data was not imported and should be corrected with the establishment data entry screen.

- Done: Closes the import dialog after the import has been completed.

III.   ADMS Supply Chains

A. Access from the Tools Menu

Direct access to the ADMS Supply Chains book is available at any time from the Tools option in the menu bar.

Accessing the ADMS Supply Chain book from the Tools menu allows you to see all the currently entered supply chain items.

The ADMS Supply Chain List displays all the ADMS supply chain items for the selected Document and/or Establishment. The list contains the Document and Establishment references, Role/Entity/Qualifier, CVM Operational Status, Sponsor New Operational Status, Approved Submission ID, Use Code, Substance, Master File reference, and the date the information was last updated. The list title contains a count of the supply chain items currently included within the list. In addition, internal sponsor comments are displayed for the selected supply chain item.

Note: To view supply chain items currently linked to a Document and/or Establishment, you must first select a Document and/or Establishment from the search criteria. Establishments are selected from the ADMS Establishment book, while Documents are either selected from the Product book (i.e., NADA, ANADA, INAD, JINAD) or the Master File book (i.e., VMF).

The following options are available:

- Copy/Move To: Allows for copying or moving selected supply chain items to another document or establishment.
  - If the current search criteria is based on a Document then the option supports copying or moving to another Document. However, you cannot copy or move items between master files and other document types.
  - If the current search criteria is based on an Establishment then the option supports copying or moving to another Establishment.
  - The Supply Chain list supports singular and multi-selection for identifying the items to be copied or moved.
- View: Displays all details related to the selected supply chain item(s) in the list.
- Import: Allows for new/updated supply chains to be inserted from an Excel spreadsheet
- New: Allows for new supply chain items to be added to the list.
- Edit: Allows for details on the selected supply chain item to be updated.
- Delete: Allows for the selected supply chain item(s) to be permanently deleted from the list.

B. Search/Sort Criteria

The Search capability allows for filtering ADMS supply chain items within the supply chain list by Document and/or Establishment. The supply chain list is initially empty until a Document or Establishment is selected. View options are available to display details of the selected Document or Establishment. A Clear option is provided to clear the search selections and the list.

1. Select a Document

Click on either the Select PD or Select MF buttons to open the Product Description or Master File Selection dialog, depending on the type of document to be selected.

2. Select an Establishment

Click on the Select button for an establishment to open the ADMS Select Establishment dialog containing the stored establishments from the ADMS Establishment book.

The Sort capability controls the ordering of supply chain items within the list. The sort orders available include Document, Establishment, Role/Entity/Qualifier, CVM Operational Status, New Operational Status, Substance, and Master File Document. The supply chain list will be reordered whenever a sort order is selected. The default sort order is Establishment when a Document is selected and Document when an Establishment is selected.

C. New Supply Chain Role

Note: New supply chain items cannot be added until a Document and/or Establishment has been selected. Without preselecting a Document or Establishment one cannot view which supply chain items already exists before adding new supply chain items.

You may add a supply chain role association between a document and establishment. To add a supply chain role, either the Document or Establishment must be selected first. You

must have an entry in the Product or Master File book for the document and an entry in the ADMS Establishment book for the establishment. If the document does not exist with the Product or Master File book, you cannot enter the Document Reference to a supply chain role. Similarly for an Establishment Reference.

Once both a document and establishment reference are selected, fill out the supply chain information section.

The accessibility of the Qualifier field is dependent on the selected Role and Entity.

The CVM Operational Status is set by CVM during a submission review containing the ADMS information and returned to the sponsors as part of the final review package sent back to the sponsor when the review is completed.

The Operational Status is set by the sponsor to inform CVM of any changes in the supply chain status.

Master files can be associated with a supply chain role by selecting yes there is an associated mater file. Click on the select button to open the Select Master File dialog that contains information from the Master File book. Select the appropriate master file from the list by double clicking on the entry in the list or highlighting it and clicking Select.

If you select Drug Substance as the entity, the Substance Reference field is activated. When referencing a substance, click on select next to Substance, and a pop-up window will appear for substance selection. To enter the substance information from the FDA substance registration system you can perform a keyword search using either by name or UNII code. The link to the FDA Substance Registration System (SRS) is also provided on this screen. The other option is to enter a substance manually by activating the manual entry button. A substance should only be entered manually when it doesn't yet exist within the SRS.

Adding internal Supply Chain Role comments allows you to capture additional information for overall management and identification of supply chain information. This information is not transmitted to CVM.

D. Missing Information

Users may select OK at any point in the supply chain entry process after the required fields are entered, even with incomplete information. A confirmation message will be displayed that provides details on which fields have not been filled out.
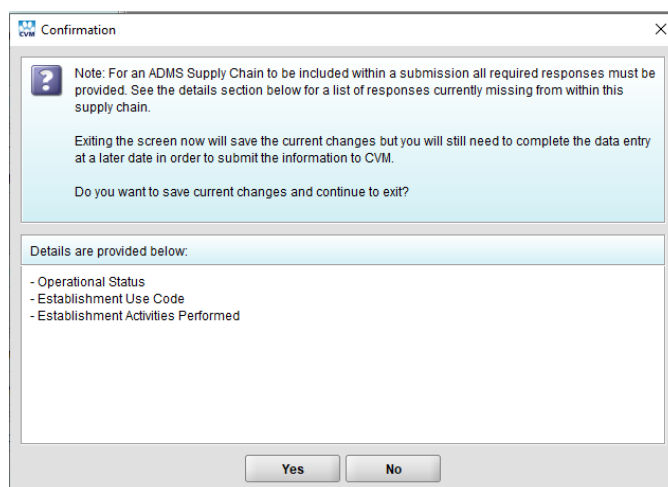
Note: For an ADMS Supply Chain to be included within a submission, all required responses must be provided.

E. Add Another Supply Chain

After completing a supply chain entry, if you have additional supply chains to add, select the Add Another Supply Chain button. Making this selection will save the previous information and clear the form to enable the entry of the next supply chain entry.

F. Add Another Role

After completing a supply chain entry, if you have additional supply chains to add that contain the same basic information as displayed within the form, except for the role information, select the Add Another Role button. Making this selection will save the previous information and display a dialog enabling the entry of the role, entity, and qualifier

information representing the new role. Once completed, you will be returned to the form to review and accept the new role.

G. Edit Supply Chain

Allows for details on the selected supply chain to be updated. Supply chain information can be edited by first selecting the desired supply chain from the list, and then selecting Edit. Alternatively, you can double-click the supply chain item in the list to open the same window. On this screen, the supply chain information can be edited. To save any edits, simply select OK when finished. You can also add new roles for the supply chain from the Edit screen.

H. Delete Supply Chain

To delete a supply chain entry, select the desired item from the list, and select Delete at the bottom of the form. A warning message will appear to confirm the deletion, which after doing so, will remove the supply chain from the list.
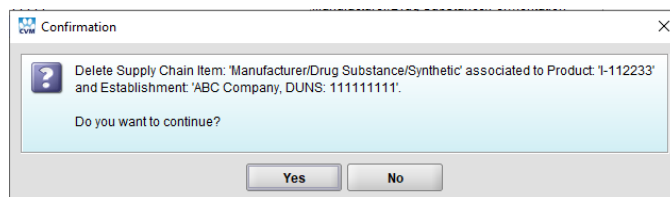
I. View ADMS Supply Chain Listing Report

Users have the option of viewing the ADMS Supply Chain Listing report for selected supply chain items, or all supply chain items within the list. Select the View button after selecting the desired supply chain items. The supply chain list supports multi-select using "Ctrl" or "Shift". The file will open in your default html viewer.

J. Import ADMS Supply Chains

Users have the option of importing supply chains from an Excel spreadsheet using common copy and paste operations. A sample spreadsheet file for importing supply chains has been provided within the "import" subfolder of the application folder. In addition, a link to the file has been provided within the hint located at the top of the supply chain list dialog. Once selected, the Copy/Paste ADMS Supply Chain Import Wizard dialog will be displayed.

For additional information on importing supply chains, see the section on importing establishments. The steps are the same, it is only the content being imported that is different.

IV. Including ADMS Establishment Information within a Submission

Previously, establishment information was collected in various locations within the chemistry, manufacturing, and controls sections of a submission based on the submission type (e.g., drug substance, drug product). Now, all establishment information is collected within a single section, under the ADMS Establishment Information tab, regardless of the submission type. In addition, establishment information is no longer entered directly into the submission, but selected from the ADMS book to ensure consistency of information across submissions, as well as to make building a submission more efficient.

	Item	Establishment	Supply Chain Role/Entity/Qualifier	Operational Status (CVM)	New Operational Status
➤	1	ABCDEF Company, DUNS: 111111111	Labeler/Drug Product		Pending
	2	ABCDEF Company, DUNS: 111111111	Manufacturer/Drug Product		Pending
	3	ABCDEF Company, DUNS: 111111111	Manufacturer/Intermediate		Pending
	4	ABCDEF Company, DUNS: 111111111	Particle Size Reducer/Excipient		Pending
	5	YYYY Facility, DUNS: Undefined	Labeler/Drug Product		Pending
	6	YYYY Facility, DUNS: Undefined	Labeler/Other		Pending
	7	YYYY Facility, DUNS: Undefined	Manufacturer/Drug Product		Pending
	8	YYYY Facility, DUNS: Undefined	Manufacturer/Intermediate		Pending
	9	YYYY Facility, DUNS: Undefined	Particle Size Reducer/Excipient		Pending

Note: In preparation for a submission, ADMS information should be added within the ADMS books so that it can be easily selected for inclusion within a submission. Also, the document type and number should be specified within section 1.0 "Document Information" of the CVM ONADE Submissions tab.

The following options are available:

- Add: Displays the ADMS book, allowing for the selection of ADMS information to be included within the submission list. The list will default to the document type and number listed in section 1.0 "Document information" of the submission.

- Delete: Deletes the selected ADMS item from the submission list. However, it does not remove it from the ADMS book.

- Delete All: Deletes all ADMS items from the submission list. However, it does not remove them from the ADMS book.

- View: Displays a detailed report of all ADMS items included within the submission list for review.

- Edit Establishment: Supports editing of the Establishment information for the selected ADMS item within the submission list. Note: Any changes made will also be reflected within the ADMS book.

- Edit Supply Chain: Supports editing of the Supply Chain information for the selected ADMS item within the submission list. Note: Any changes made will also be reflected within the ADMS book.

- Refresh: Refreshes the contents of the list. This can be useful when making changes directly within the ADMS book and reflecting the updates to items included within the ADMS submission list.

V.   Importing ADMS Establishment Information Received within a CVM Response

CVM may update aspects of the ADMS establishment and supply chain information (e.g., operational status, approved submission ID, address information) during the review of any submission containing ADMS information. The CVM updates of the ADMS information will subsequently be sent back to sponsors as part of the standard CVM Response Acknowledgment after a review is completed. The CVM Response Acknowledgment is represented as a ZIP file transmitted to the sponsor through the FDA ESG.

The purpose of CVM updating the ADMS information and transmitting it back to sponsors is so sponsors can import the updates into their eSubmitter ADMS books for use in the next related submission. Thus, synching the ADMS information between sponsors and CVM, as well as alleviating the time burden of CVM reviewing future submissions containing ADMS information unchanged from a previously received and reviewed submission.

The process of importing ADMS information from a CVM Response Acknowledgment is as follows:

1. Select the "Import..." option from the eSubmitter Tools menu.
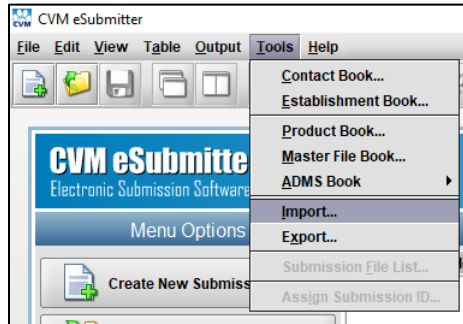
2. Select the "CVM Response Acknowledgment (zip file) into the ADMS Book" option as the Import Type
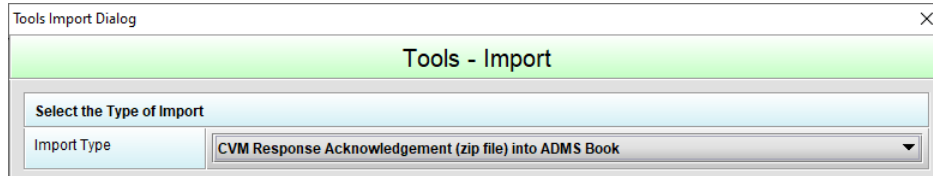
3. Select the CVM response file (zip file) containing ADMS information to be imported by clicking the folder option, navigating to the folder containing the zip file, selecting the file, and clicking the "Select" option to choose the file.
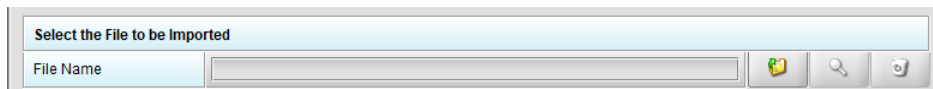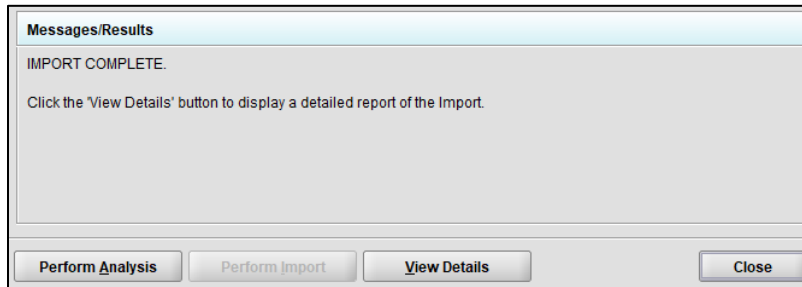
4. Click the "Perform Analysis" button to see a summary of the analysis. There are three possible results from the analysis:

   o A message that no ADMS information was detected to be imported

   o A message that ADMS information was detected but no changes were identified

   o A high-level summary of the ADMS changes to be imported
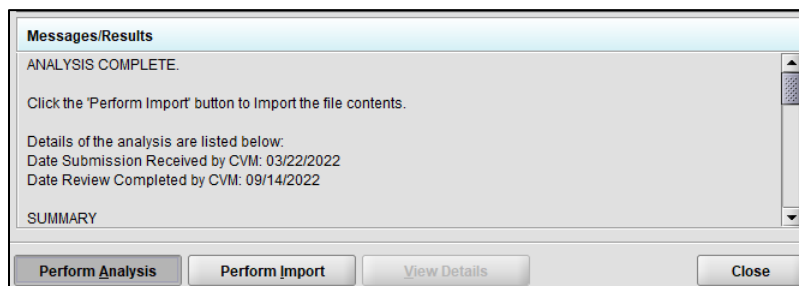
5. If the analysis identified ADMS information to be imported, the "Perform Import" option will be enabled. Click the "Perform Import" button to import the changes to

the ADMS books. Once the import has been completed, a message will display providing instructions on how to view a detailed report of the changes made.

Messages/Results

IMPORT COMPLETE.

Click the 'View Details' button to display a detailed report of the Import.

| Perform Analysis | Perform Import | View Details | Close |

6. Click the "View Details" button to open a detailed report of the changes made.