

CVM eSubmitter

Animal Drug and Manufacturing (ADMS) Book Quick Guide

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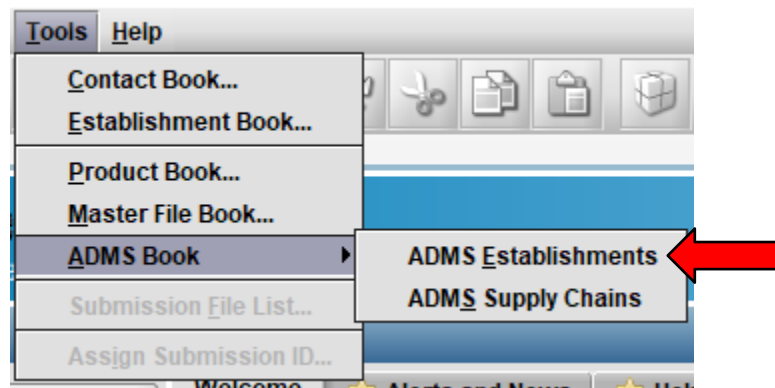
I. Introduction

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, 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.

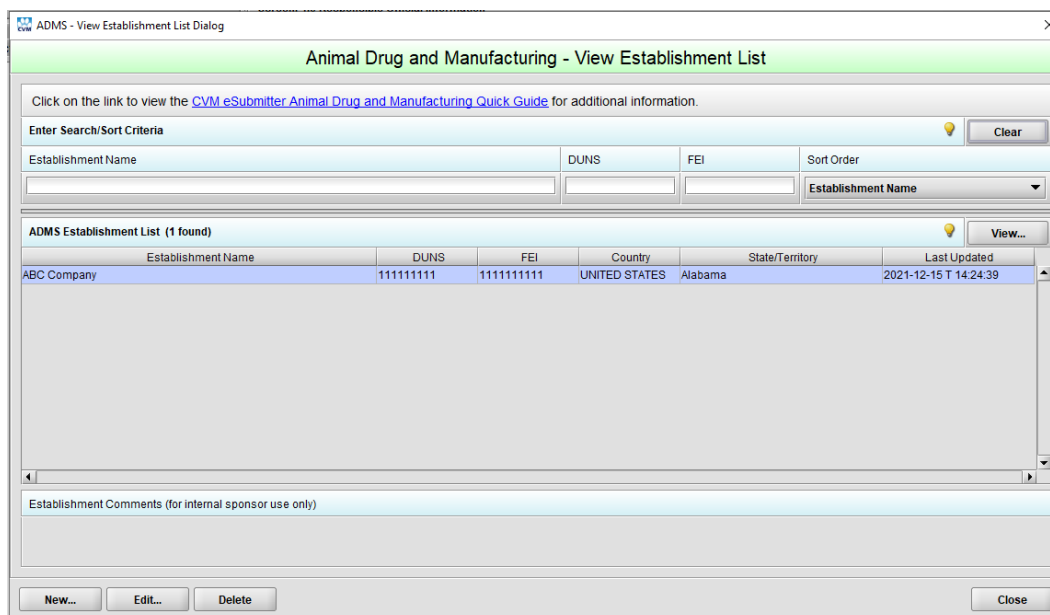
II. ADMS Establishments Book

A. Access from the Tools Menu

Direct access to the 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 of the currently entered establishments.



Establishment Name	DUNS	FEI	Country	State/Territory	Last Updated
ABC Company	111111111	111111111	UNITED STATES	Alabama	2021-12-15 T 14:24:39

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.

- 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.

Enter Search/Sort Criteria			
Establishment Name	DUNS	FEI	Sort Order
<input type="text"/>	<input type="text"/>	<input type="text"/>	Establishment Name ▼

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.

ADMS - Add Establishment Dialog

Animal Drug and Manufacturing - Add Establishment

Establishment | Inspection | Contact


Establishment related details

Establishment

Establishment Name:

D&B D-U-N-S Number:

FEI Number:

 The FEI number is needed by the Agency to proceed with the facility evaluation portion of the application assessment. The absence of the FEI number may hinder the timeline for assessment of the establishment information where needed for determination of conformance with CGMPs.

Address

Country:

Address - Line 1:

Address - Line 2:

City:

State, Province, Territory:

Postal Code:

Phone Numbers

Telephone Number: Ext:

Fax Number:

Establishment Comments (for internal sponsor use only)

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.

ADMS - Add Establishment Dialog

Animal Drug and Manufacturing - Add Establishment

Establishment Inspection Contact

Inspection related details

Inspection Information

Current FDA Inspection Status

Inspection End Date (MM/DD/YYYY)

Additional information about the GMP status of the establishment

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.

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.

E. Contact Details

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

ADMS - Add Establishment Dialog

Animal Drug and Manufacturing - Add Establishment

Establishment Inspection Contact

Contact related details

Contact

Copy from Contact Book...

Title (e.g., Mr., Ms., Dr.):

First/Given Name:

Middle Name:

Last Name:

Email Address:

Address

Copy from Establishment Address...

Country:

Address - Line 1:

Address - Line 2:

City:

State, Province, Territory:

Postal Code:

Phone Numbers

Telephone Number:

Fax Number:

Previous Next Add Another Establishment OK Cancel

In addition, the following capabilities are provided:

- Copy from Contact Book (Only Add Mode): 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.

The image shows a 'Confirmation' dialog box with a question mark icon. The text inside reads: 'Note: For an ADMS Establishment to be included within a submission all required responses must be provided. See the details section below for a list of responses currently missing from within this establishment. Exiting the screen now will save the current changes but you will still need to complete the data entry at a later date in order to submit the information to CVM. Do you want to save current changes and continue to exit?'. Below this is a section titled 'Details are provided below:' containing three categories of missing information: ESTABLISHMENT (Address - Line 1, City, Postal Code, Telephone Number), INSPECTION INFORMATION (Current FDA Inspection Status, Inspection End Date (MM/DD/YYYY)), and CONTACT (Title (e.g., Mr., Ms., Dr.), First/Given Name, Last Name, Email Address, Country, Address - Line 1, City, State, Province, Territory, Postal Code, Telephone Number). At the bottom are 'Yes' and 'No' buttons.

Note: For an ADMS Establishment to be included within a submission, all required responses must be provided.

G. Add Another Establishment

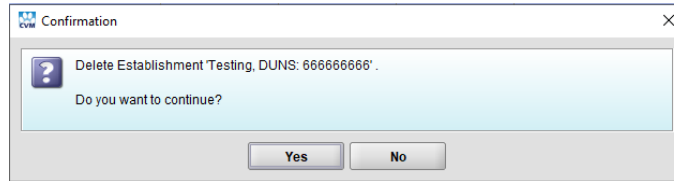
After completing an establishment entry and selecting OK, if you have additional establishments to add, select the Add Another Establishment button. Making this selection will clear the form to enable the entry of the next establishment.

H. Edit ADMS Establishment

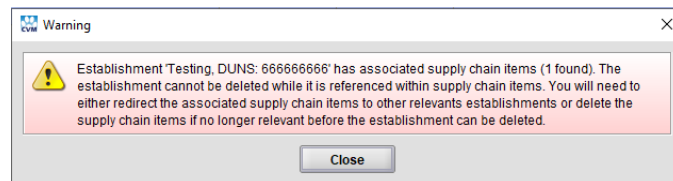
Allows for details on the selected establishment to be updated. Establishment information can be edited by first selecting the desired establishment from the ADMS Establishment List, and then selecting Edit. Alternatively, you can double-click the establishment name in the list to open the same window. 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 a facility, select the desired facility 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.

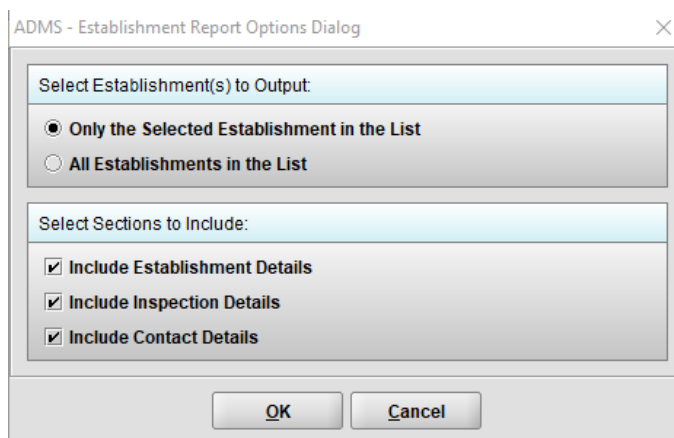


If an establishment is associated with a supply chain item, you will not be able to delete it without either redirecting the associated supply chain items to other establishments or deleting the supply chain items.



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 facility. The dialog box which opens gives the option to select which establishments to output.

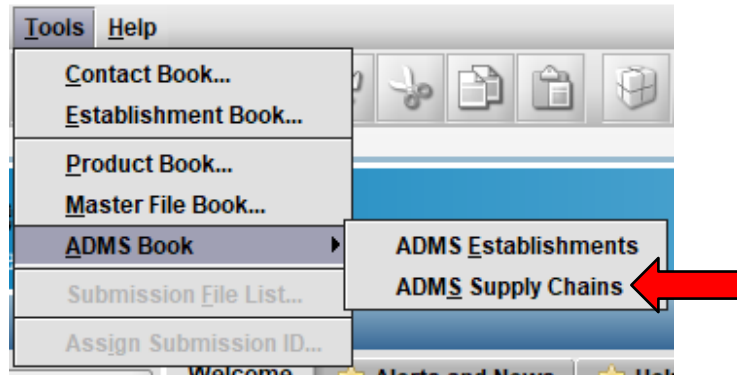


Only a single establishment or all establishments can be selected; multiple establishments cannot be selected using "Ctrl" or "Shift". After selecting which sections should be included in the report, the file will open in your default html viewer.

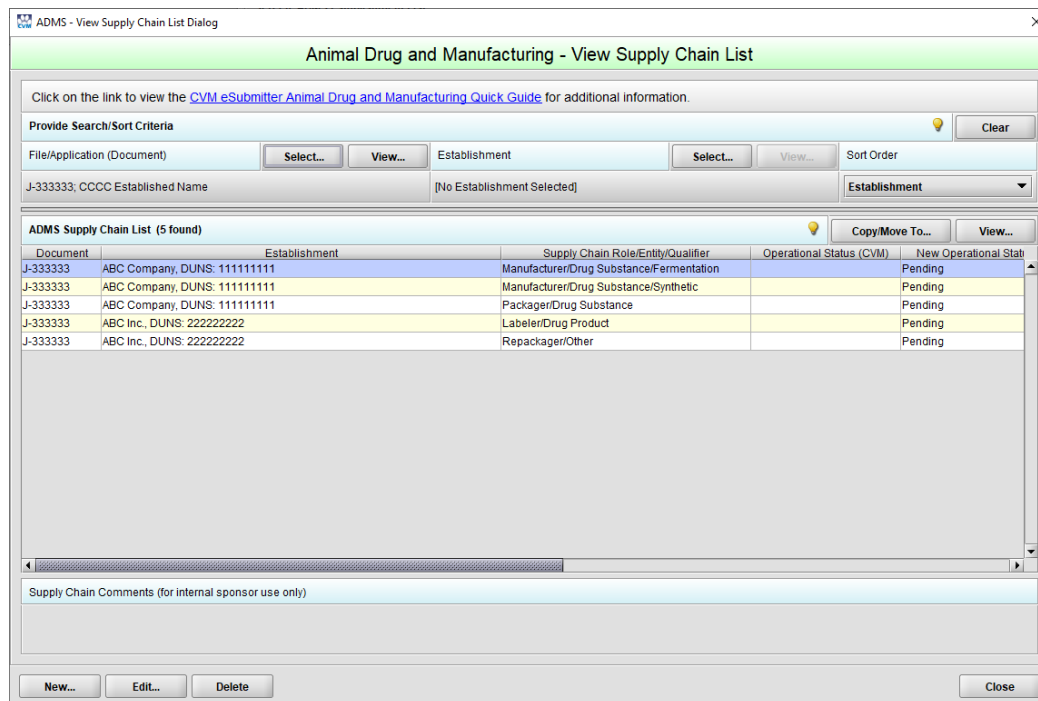
III. ADMS Supply Chains

A. Access from the Tools Menu

The ADMS Supply Chains book can be accessed in two ways. Direct access to the books 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 of the currently entered supply chain items.



The ADMS Supply Chain List displays all the ADMS supply chain items for the selected File/Application 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.

The following options are available:

- Copy/Move To: Allows for copying selected supply chain items to another file/application or establishment.
 - If the current search criteria is based on a File/Application then the option supports copying or moving to another File/Application.

- 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.
- 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.

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

1. Select a File/Application (Document)

Click on the Select button to open the Product Description Selection dialog containing the stored File/Application information from the Product Book.

2. Select an Establishment

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

B. Search/Sort Criteria

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

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 File/Application is selected and Document when an Establishment is selected.

C. New Supply Chain Role

You may add a supply chain role association between an establishment and application/file. To add a supply chain role, either the File/application or Establishment must be selected first. You must also have an entry in the Product Book. If the file/application does not exist with the product book, you cannot enter the File/Application Reference to a supply chain role.

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

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.

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.

ADMS - Add Supply Chain Dialog

Animal Drug and Manufacturing - Add Supply Chain

File/Application Reference Select... View...

I-112233; Test Drug

Establishment Reference Select... View...

ABC Company, DUNS: 11111111

Supply Chain Information

Role

Entity

Qualifier

Operational Status (CVM) [Not Yet Assigned By CVM]

Operational Status

Approved Submission ID

Master File Reference

Is there an associated master file?

☐ Yes

☐ No

Master File Reference Select... View...

[No Master File Selected]

Substance Reference Select...

[Substance Not Available for Selection]

Additional Information

Establishment Use Code

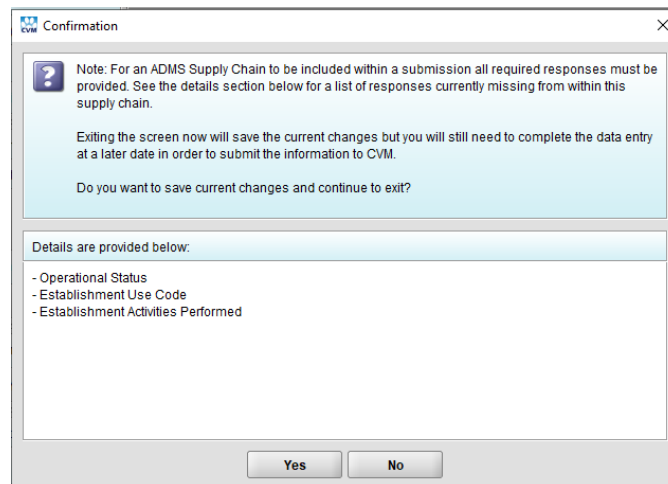
Establishment Activities Performed

Supply Chain Role Comments (for internal sponsor use only)

Add Another Supply Chain OK Cancel

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

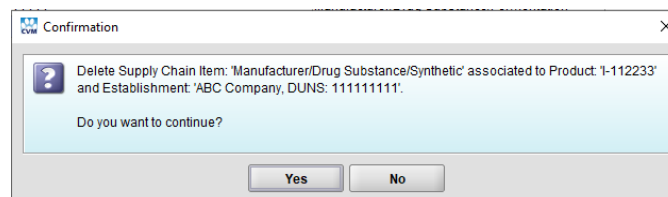
After completing a supply chain entry and selecting OK, if you have additional supply chains to add, select the Add Another Supply Chain button. Making this selection will clear the form to enable the entry of the next supply chain entry.

F. 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 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.

G. 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.










H. View ADMS Supply Chain Listing Report

Users have the option of viewing the ADMS Supply Chain Listing report for a selected establishment, or for all establishments within the list. Select the View button after selecting the desired supply chain. The dialog box which opens gives the option to select which supply chains to output.

Only a single supply chain in the list or all supply chains in the list can be selected; multiple supply chains cannot be selected using "Ctrl" or "Shift". The file will open in your default html viewer.

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.

Select the Establishment/Supply Chain information for all facilities relevant to this submission.				
<div>      </div>				
9 found in the list (1 required)				
>	Item	Establishment	Supply Chain Role/Entity/Qualifier	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.
- Delete: Deletes the selected ADMS item from the submission list.
- Delete All: Deletes all ADMS items from the submission list.
- 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 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 submission list.