



FDA CVM eSubmitter Master File User Guide

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FDA CVM eSubmitter Master File



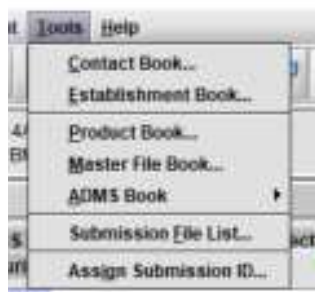
Introduction

The Master File Book provides a means of storing Master File information to be reused across submissions and

associated books. Reusing this data makes building a submission more efficient, as well as ensuring data consistency across submissions.

Accessing the Master File Book

The Master File book can be accessed in multiple ways. Direct access to the book is available at anytime from the Tools option in the menu bar.



In addition, the Master File book can be accessed from the Master File Description tab of a submission, and associated sections within CMC and VMF submissions using a Master File interface questions listed within the submission.

Selecting a Master File from within a submission

A screenshot of a web-based form titled 'Master File Description'. It contains several sections: 'Please enter the master file related information below (or use the buttons to the right to access previously saved master file information)', 'Select the Type of VMF' with a dropdown menu showing 'Type II', 'Subject of the Master File' with a text input field containing 'BENZHYDRIYL PENICILLIN V KALFONDE (HAWKINS)', and 'Information Covered in the Master File' with a text input field. On the right side of the form, there are three buttons: 'Select...', 'View...', and 'Cancel'.

Selecting a Master File from with a Supply Chain item

A screenshot of a software dialog box titled 'ADMS - Edit Supply Chain Dialog'. It contains several sections: 'File/Application Reference' with a text input field containing 'S-112233 Test Drug', 'Establishment Reference' with a text input field containing 'ABC Company, DUNS: 111111111', 'Supply Chain Information' with a table containing columns for 'Role', 'Drug Substance', 'Formulation', 'Operational Status (CVM)', 'Operational Status', and 'Approved Submission ID', 'Master File Reference' with a section titled 'Is there an associated master file?' and a radio button selected for 'Yes', and 'Substance Reference' with a text input field containing 'PENICILLIN G PROCANE (1TR794E31N)'. There are 'Select...' and 'View...' buttons next to the first two sections.

Regardless of the method used to access the master File book, the View Master File List Dialog will open.

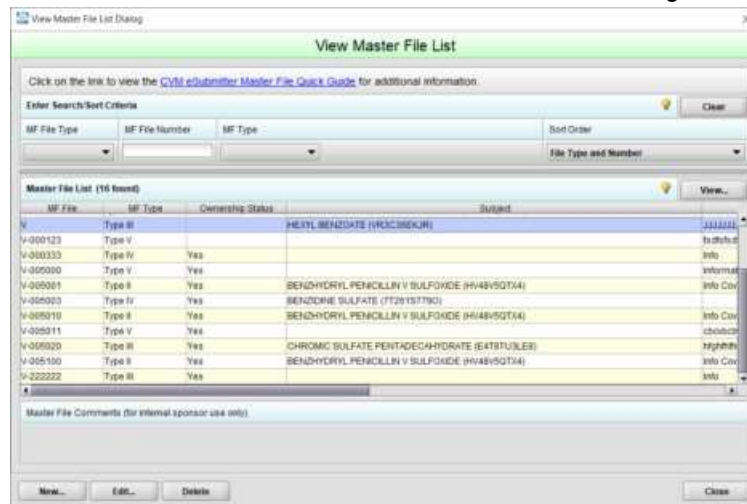
A. The Master File List

The Master File List displays all the master files matching the search criteria, or all master files available when no search criteria are provided. The list contains the MF File, MF Type, Ownership Status, Subject, Information Covered, and the date the information was last updated. The list title contains a count of the master files currently included within the list. In addition, internal sponsor comments are displayed for the selected master file.

The following options are available:

- View: Displays all details related to the selected master file.
- New: Allows for new master files to be added to the list.
- Edit: Allows for details on the selected master file to be updated.
- Delete: Allows for the selected master file to be permanently deleted from the list.

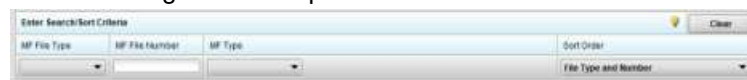
There are two modes for displaying the Master File List. The first is the View mode, which is used to manage the overall contents of the master file list. The View mode is available within the application Tools menu. The second is the Select mode, which is used to select a master file as a reference (e.g., to supply chain information). The Select mode is available from within the data screen where the reference is being initiated.



The default behavior of some operations is dependent on the mode used to open the Master File List. For example, in View mode using the Enter key on the keyboard or double-clicking with the mouse on the selected row initiates an Edit, while in Select mode the same operation initiates a Select.

B. Search/Sort Criteria

The Search capability allows for searching across all master files contained within the Master File List. The fields available for searching include MF File Type (VMF/DMF), MF File Number, and MF Type (Type II/III/IV/V). The search locates all master files matching all criteria provided.



The MF File Type and MF Type searches retrieve all master files matching the selections made, while the MF File Number search is based on locating all master files that begin with the digits entered.

When no search criteria are provided, all master files are listed. A Clear option is provided to clear the search criteria and reset the master file list.

The Sort capability controls the ordering of master files within the list. The sort orders available include File Type and Number, Master File Type, and Ownership Status. The master file list will be reordered whenever a sort order is selected. The default sort order is File Type and Number. The sort order will reset to the default when the Clear option is selected.

Entering Information into the Master File Book

A. Creating a New Entry

From the View Master File List Dialog, select New... to create a new entry. This will open the Add Master File Dialog.

Populate all the required fields: MF File Type (VMF/DMF), MF File Number, and MF Type (Type II/III/IV/V). Provide a file reference (i.e., folder location and file name) to the Letter of Authorization (LOA) providing Right of Reference.

Enter if the master file is owned by the firm. If so, complete the additional associated questions.

The comments field is for sponsor use only and is not included as part of any submission content. It is provided to aid sponsors in the overall management and identification of master file information by allowing the capture of additional information related to each master file.

When finished, select OK to close the dialog, or select Add Another Master File if you wish to create additional entries.

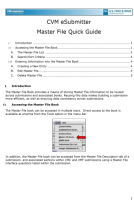
B. Edit Master File

Allows for details on the selected master file to be updated. Master File information can be edited by first selecting the desired master file from the Master File List, and then selecting Edit. Alternatively, you can double-click a master file item in the list to open the same window.

C. Delete Master File

To delete a master file, select the desired master file from the Master File 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 master file from the list.

Documents / Resources

	<p>FDA CVM eSubmitter Master File [pdf] User Guide CVM eSubmitter, Master File, CVM eSubmitter Master File</p>
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