

CVM eSubmitter

Master File Quick Guide

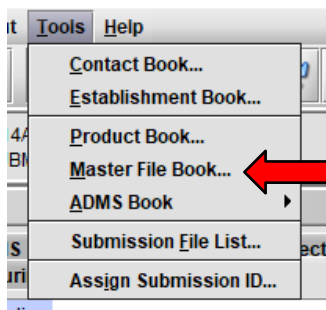
I.	Introduction	1
II.	Accessing the Master File Book.....	1
A.	The Master File List	3
B.	Search/Sort Criteria	4
III.	Entering Information into the Master File Book	4
A.	Creating a New Entry	4
B.	Edit Master File.....	5
C.	Delete Master File	5

I. 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.

II. 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

It is required that the information within the Master File Description section includes the latest Master File information available at the time of the submission. Master File Book support has been provided to aid in maintaining and managing Master File Description information across submissions. For additional details, view the hint in the Master File Book interface question below.

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:

Type II

Subject of the Master File:

BENZHYDRYL PENICILLIN V SULFOXIDE (HV48V5QTx4)

Information Covered in the Master File:

Selecting a Master File from with a Supply Chain item

ADMS - Edit Supply Chain Dialog

Animal Drug and Manufacturing - Edit Supply Chain

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

I-112233; Test Drug

Establishment Reference Select... View...

ABC Company, DUNS: 111111111

Supply Chain Information

Role	Manufacturer
Entity	Drug Substance
Qualifier	Fermentation
Operational Status (CVM)	[Not Yet Assigned By CVM]
Operational Status	Pending
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...

PENICILLIN G PROCAINE (17R794ESYN)

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

View Master File List Dialog

View Master File List

Click on the link to view the [CVM eSubmitter Master File Quick Guide](#) for additional information.

Enter Search/Sort Criteria Clear

MF File Type	MF File Number	MF Type	Sort Order
<input type="text"/>	<input type="text"/>	<input type="text"/>	File Type and Number

Master File List (16 found) View...

MF File	MF Type	Ownership Status	Subject	
V	Type III		HEXYL BENZOATE (VR3C36EKJR)	JJJJJJ
V-000123	Type V			fsdfsfsd
V-000333	Type IV	Yes		Info
V-005000	Type V	Yes		Informa
V-005001	Type II	Yes	BENZHYDRYL PENICILLIN V SULFOXIDE (HV48V5QTX4)	Info Cov
V-005003	Type IV	Yes	BENZIDINE SULFATE (7T261S779O)	
V-005010	Type II	Yes	BENZHYDRYL PENICILLIN V SULFOXIDE (HV48V5QTX4)	Info Cov
V-005011	Type V	Yes		cbcbcb
V-005020	Type III	Yes	CHROMIC SULFATE PENTADECAHYDRATE (E4T8TU3LE8)	hghhfh
V-005100	Type II	Yes	BENZHYDRYL PENICILLIN V SULFOXIDE (HV48V5QTX4)	Info Cov
V-222222	Type III	Yes		Info

Master File Comments (for internal sponsor use only)

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:

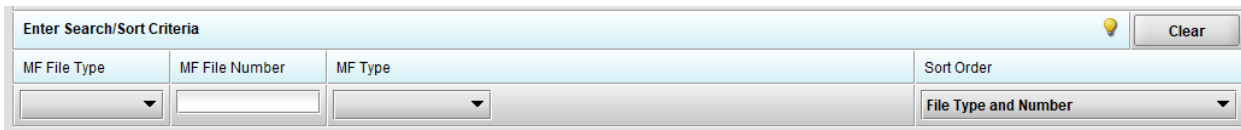
- View: Displays all details related to the selected master file.
- New: Allows for new master files to be added to the list.
- Edit: Allows for details on the selected master file to be updated.
- Delete: Allows for the selected master file to be permanently deleted from the list.

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.

III. 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.

Add Master File

Master File Reference

File Type

File Number

Master File Type

Subject of the Master File?

Master File Details

Do you own the Master File?

Yes

No

Master File Details Specific to Owned VMF's

Does the Master File include Sterile Process Validation information?

Yes

No

Public lists are at [Types II-V Veterinary Master File Lists | FDA](#)

Should this VMF be listed within CVM's public VMF list?

Yes

No

Information covered in the Master File

Add Another Master File OK Cancel

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.