CCR Number	ESUB-060
Title	Fix defect in Terminate File Request submissions (G-G-TM, I-G-TM, J-G-TM, V-G-TM) when including additional document numbers
Business Owner	CVM
Change Type	Defect
Components	CVM eSubmitter Application
Severity	High
Application Release	March 16, 2018

Previous Approach

The steps to initiating a Terminate File Request (TM) within CVM eSubmitter are to provide the lead document type (G, I, J, or V) and number to be terminated, select the combination of G-TM for the submission type and classification code, and HFV-180 for the review division. Once completed, the General Correspondence (TM) section is presented for entering the file termination details.

The file termination details include the following:

- An option for specifying additional documents to be terminated (I, J, G, and V)

- Required certification and acknowledgement text to be accepted by the sponsor
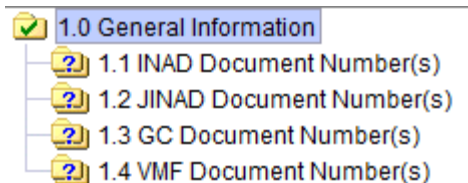
- Optional comments

The option for selecting additional documents to be terminated is within the General Information section, see below.

Which enables the individual list sections for entering the additional document numbers, based on the document types selected to be included, see below.

While INADs, JINADs, and GCs require only a document number, VMFs require a document number, as well as a reason for the request and a list of persons authorized to reference the file.

The defect within the current template form is that it fails to process the termination requests for any additional document types provided, other than INADs. In addition, currently all termination requests are directed to HFV-180, when VMF requests are reviewed by HFV-140. Lastly, the details related to a lead VMF document number are not available until later in the data entry, under the Certification section.

Change Description

The following changes have been implemented

- The defect preventing the processing of additional document types, other than INADs (i.e., G, J, and V types) has been resolved.

- The multiple list sections for collecting the additional document numbers by type have been consolidated into a single list section supporting all document types, with import capabilities included to align with the approach used for collecting document numbers in other submission types.

- VMF (V) file terminations have been separated out from other document type file terminations (i.e., G, I, and J) so that they can be properly routed to HFV-140, while the other document type file termination requests are routed to HFV-180.

- The details for a lead VMF document number are relocated to the General Information section so the responses can be captured at the beginning of the termination request.

INAD, JINAD, and GC Termination Requests
The new approach to submitting INAD, JINAD, or GC Terminate File Requests (TM) within CVM eSubmitter is to provide the lead document type (G, I, or J) and number to be terminated, select the combination of G-TM for the submission type and classification code, and HFV-180 for the review division. Once completed, the new General Correspondence (TM) section is presented for entering the file termination details.

The General Information section now only contains a single question indicating if additional document numbers are to be included, see below.

If including additional documents, there is now only one section needed to enter all additional INAD, JINAD, and GC document numbers.

For additional, INAD, JINAD, and GC files to be terminated, only the document type and number is collected.

Please select the down arrow to the right to begin the import function.

| + | − | ⬚ | List | Detail | Info | ⇦ | ⇨ | ⇧ | ⇩ |

Item: 1   Enter the additional Document Types and Document Numbers.

Document Type:

Document Number:

The Certification section has also been adjusted to allow the user to specify the appropriate affirmation response required based on the document types included.

Respond to the folloing questions based on the lead document type and number referenced within the Document Number section at the beginning of the submission, as well as all document types and numbers referenced within the Document Types and Numbers Table above.

(J)INAD Certification

Does this submission reference an INAD or JINAD file to be terminated as either the lead document for the submission or within document types and numbers table above?

◉ Yes
◯ No

➤ Check the box to affirm that for each (J)INAD file:
- I do not intend to conduct a bona fide scientific investigation for the purpose of seeking approval of any new animal drug covered by these (J)INAD file(s),
- I am not aware of any approved or pending application (NADA or ANADA) that relies on or references the information contained in these file(s), and
- I waive my right to a hearing under 21 CFR Part 16 regarding the termination of these investigational exemption(s).

GC Certification

Does this submission reference a GC file to be terminated as either the lead document for the submission or within the document types and numbers table above?

◉ Yes
◯ No

➤ Check the box to affirm that for each GC file:
- I am not aware of any approved or pending application (NADA or ANADA) that relies on or references the information contained in these file(s).

No changes were made to either the Acknowledgement or Comments sections.

VMF Termination Requests
The new approach to submitting a VMF Terminate File Request (TM) within CVM eSubmitter is to provide the lead document type (V) and number to be terminated, select the combination of G-TM for the submission type and classification code, and HFV-140 for the review division. Once completed, the new General Correspondence (TM) section is presented for entering the file termination details.

The General Information section now contains details related to the lead VMF document file to be terminated (i.e., reason for the request, a list of persons authorized to reference the file, and an affirmation that all persons authorized to reference have been notified), as well as a question indicating if additional VMF document numbers are to be included, see below.

Please review the specifications for file attachments in the CVM eSubmitter File Specification Quick Guide.
Provide details for the VMF Document Number referenced within the Document Number section at the beginning of the submission
Provide the reason for the request to close the file: ⬤
Provide a current list of persons authorized to reference the file in the memo field below. If you wish to provide the list as an attached file, ⬤ press the ADD (+) button to attach the file and type "See attachment" in the memo field. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above).
File Attachment ➕ ➖ 🔍 ⓘ
Check the box to affirm you have notified each person who is authorized to reference this file, that this file will be closed. ⬤ ☐
Does this request apply to additional VMF Documents? ⬤
⚪ Yes
⚪ No

If including additional VMF documents, there is now only one section needed to enter all additional VMF document numbers and details.

- 📁 1.0 General Information
  - 📁 1.1 Document Types and Numbers Table
- ☑ 2.0 Acknowledgement
- ☑ 3.0 Comments

For additional VMFs, the document type and number, reason for the request, a list of persons authorized to reference the file, and an affirmation that all persons authorized to reference have been notified is required.

There is no separate Certification section for VMF file terminations since affirmation for each VMF is included and required within the VMF details. No changes were made to either the Acknowledgement or Comments sections for VMFs.

CVM eSubmitter
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Document Type: ●

VMF ▼

Document Number: ●

Please review the specifications for file attachments in the CVM eSubmitter File Specification Quick Guide.

Details for the selected VMF Document Number

Provide the reason for the request to close the file: ●

Provide a current list of persons authorized to reference the file in the memo field below. If you wish to provide the list as an attached file, press the ADD (+) button to attach the file and type "See attachment" in the memo field. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above). ●

File Attachment ➕ ➖ 🔍 ℹ️

Check the box to affirm you have notified each person who is authorized to reference this file, that this file will be closed. ● ☐