

CCR Number	ESUB-056
Title	Revised INAD Effectiveness and Target Animal Safety Technical Sections for I-P-EF and I-P-TS submission types
Business Owner	CVM
Change Type	Enhancement
Components	CVM eSubmitter Application
Severity	High
Application Release	March 16, 2018

Previous Approach

The steps to creating an INAD Effectiveness or Target Animal Safety technical section submission within CVM eSubmitter are to select the combination of I-P-EF or I-P-TS for the document type, submission type and classification code. Once completed, the appropriate technical section is presented for data entry.

The previous design of the data entry for completing INAD Effectiveness and Target Animal Safety technical sections was simply to select a study type and attach all the related files at one time. See below for an example of the data entry for a Field Safety Study.

Please review the specifications for file attachments in the [CVM eSubmitter File Specification Quick Guide](#).

➤ The Field Safety Study data/information should be attached below. Provide study reports and copies of raw data in bookmarked Portable Document Format (.pdf) files. Any data files, statistical analysis programs and documentation, and summary tables provide as eXtensible Markup Language (.xml) files or SAS System XPORT (.xpt) files. Press the ADD (+) button below to attach each file. The PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above).

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The only difference between the Effectiveness and Target Animal Safety technical sections are the study types supported.

The study types supported for Effectiveness are:

What data/information are you submitting (select all that apply)?

- Field Study
- In Vitro Study
- Laboratory Study
- Palatability Study
- Pharmacokinetic Study
- Dosage Characterization
- Other; Unclassified Study

The study types supported for Target Animal Safety are:

What data/information are you submitting (select all that apply)?	<input checked="" type="checkbox"/> Margin of Safety Study <input checked="" type="checkbox"/> Reproductive Safety Study <input checked="" type="checkbox"/> Field Safety Study <input checked="" type="checkbox"/> Ocular Safety Study <input checked="" type="checkbox"/> Pharmacokinetic Study <input checked="" type="checkbox"/> Injection Site Study <input checked="" type="checkbox"/> Interchangeability Study <input checked="" type="checkbox"/> Compatability Study <input checked="" type="checkbox"/> Tolerance Study <input checked="" type="checkbox"/> Other; Unclassified Study <input checked="" type="checkbox"/> Toxicological Characterization <input checked="" type="checkbox"/> Human User Safety
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The two primary issues within the previous design were:

1. Lack of a comprehensive structure in collecting the information from the sponsor and presenting the information clearly to reviewers
2. Did not delineate study information between multiple studies of the same types (e.g., multiple field safety studies)

Change Description

The following changes have been implemented within the revised templates

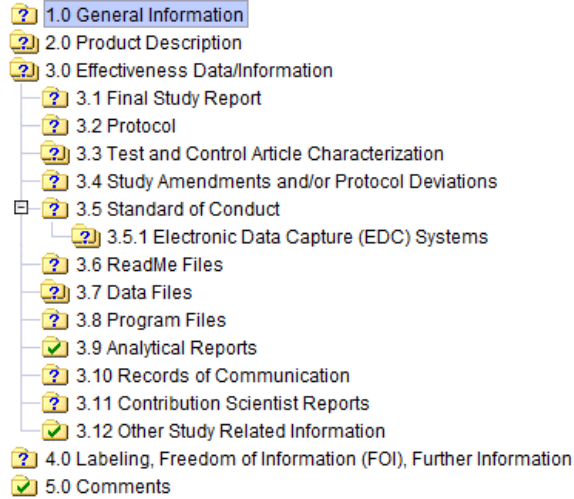
- Defines a comprehensive structure based on the technical section and study type selected that includes as many as 13 sub-sections of content to be collected per study
 - Final Study Report
 - Protocol
 - Study Amendments and/or Protocol Deviations
 - Standard of Conduct
 - Electronic Data Capture (EDC) Systems
 - ReadMe Files
 - Data Files
 - Program Files
 - Analytical Reports
 - Records of Communication
 - Contribution Scientist Reports
 - Test and Control Article Characterization
 - Other Study Related Information

- Supports an unlimited number of studies, including multiple studies of the same type, that are individually structured

The next two sections focus on the unique data entry characteristics related to each technical section (i.e., the organization of the technical section, the study types available, and the status of each study sub-section as it correlates to a study type). The remaining sections provide the details on each aspect of the structure that is common across technical sections.

Effectiveness Data/Information Technical Section

The Effectiveness Data/Information Technical Section has the following structure.



Effectiveness studies are added within Section 3.0 “Effectiveness Data/Information,” while sub-sections 3.1 through 3.12 are completed individually for each study, in accordance to the study type selected. The remaining sections (i.e., 1.0, 2.0, 4.0, and 5.0) are completed once for the entire technical section.

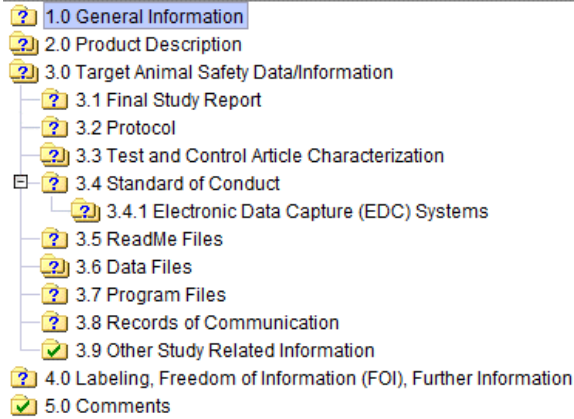
The following table identifies the sub-sections enabled for each Effectiveness study type. Unless otherwise specified, the responses within the study sub-sections are required.

EF Study Type	EF Sections Included
Field Study	Final Study Report
In Vitro Study	Protocol
Laboratory Study	Test and Control Article Characterization
Palatability Study	Study Amendments and/or Protocol Deviations
Pharmacokinetic Study	Standard of Conduct
	Electronic Data Capture (EDC) Systems
	ReadMe Files
	Data Files
	Program Files
	Analytical Reports (optional)
	Records of Communication
	Contribution Scientist Reports
	Other Study Related Information (optional)

EF Study Type	EF Sections Included
Literature	Standard of Conduct (optional) Electronic Data Capture (EDC) Systems (optional) ReadMe Files (optional) Data Files (optional) Program Files (optional) Analytical Reports (optional) Other Study Related Information (optional)
Dosage Characterization Other; Unclassified Study	Other Study Related Information (optional)

Target Animal Safety Data/Information Technical Section

The Target Animal Safety Data/Information Technical Section has the following structure.



Target Animal Safety studies are added within Section 3.0 “Target Animal Safety Data/Information,” while sub-sections 3.1 through 3.9 are completed individually for each study, in accordance to the study type selected. The remaining sections (i.e., 1.0, 2.0, 4.0, and 5.0) are completed once for the entire technical section.

The following table identifies the sub-sections enabled for each available Target Animal Safety study type. Unless otherwise specified, the responses within the study sub-sections are required.

TS Study Type	TS Sections Included
Margin of Safety Study	Final Study Report
Reproductive Safety Study	Protocol
Field Safety Study	Test and Control Article Characterization
Ocular Safety Study	Standard of Conduct
Pharmacokinetic Study	Electronic Data Capture (EDC) Systems
Injection Site Study	ReadMe Files
Interchangeability Study	Data Files
Compatibility Study	Program Files
Tolerance Study	Records of Communication
	Other Study Related Information (optional)

TS Study Type	TS Sections Included
Literature	Standard of Conduct (optional) Electronic Data Capture (EDC) Systems (optional) ReadMe Files (optional) Data Files (optional) Program Files (optional) Other Study Related Information (optional)
Toxicological Characterization Human User Safety Other; Unclassified Study	Other Study Related Information (optional)

Technical Section Contents

The following sub-sections detail the content collected within each section of the template form. The tables in the previous section identify which sub-sections are enabled for each type of study, and when the content within each sub-section is considered required or optional. Unless otherwise stated, all items within a sub-section are relevant to both types of technical section submissions.

A. General Information

This section documents the information captured for General Information.

Please select the final action letter you are requesting from CVM with this submission: 💡

Submitted Information Acceptable; Technical Section Incomplete

Technical Section Complete

Is this in response to a previous CVM Technical Section Incomplete Letter? 🔵

Yes

No

Please review the specifications for file attachments in the [CVM eSubmitter File Specification Quick Guide](#).

If you have a cover letter please press the ADD (+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above).

File Attachment + - 🔍 ?

Please press the ADD (+) button to attach a single PDF file that contains the submission contents information. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above).

File Attachment + - 🔍 ?

Provide a summary of the information provided in this submission: 🔵

Note: The question within this section supporting a file attachment for Submission Content Information is only available for Effectiveness Technical Section submissions.

There are two different approaches to data collection within a technical section submission based on the response to the “Is this in response to a previous CVM Technical Section Incomplete Letter?” question.

If the response is:

- No: The data collection follows the standard approach where sub-sections are presented consistently for each technical section and study type, as documented in the previous tables.
- Yes: New questions are presented within the General Information section related to the technical section incomplete letter, as well as an option is presented within the study data information section to specify just the sub-sections included within each study that are relevant to the technical section incomplete letter response.

Presented below are the additional questions related to a technical section incomplete letter response.

Is this in response to a previous CVM Technical Section Incomplete Letter? ⓘ	
<input checked="" type="radio"/> Yes <input type="radio"/> No	
➤	In the Technical Section Incomplete Letter referenced above, did CVM offer you a shortened review time with the resubmission of this Technical Section? ⓘ💡
<input type="radio"/> Yes <input type="radio"/> No	
➤	Please provide the CVM Submission Number associated with the referenced Technical Section Incomplete Letter: ⓘ💡
<input type="text"/>	
➤	Are there any additional CVM Submission Numbers associated with your CVM Technical Section Incomplete Letter(s)? ⓘ
<input type="radio"/> Yes <input type="radio"/> No	
ⓘ Please provide a description of the updates included as part of your response to the technical incomplete letter. Include any impacted studies in section 3.0 "Effectiveness Data/information", only providing updates to sections 3.1 through 3.12, as needed.	
➤	Please press the ADD (+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above). ⓘ
File Attachment	<input type="button" value="+"/> <input type="button" value="-"/> <input type="button" value="🔍"/> <input type="button" value="ⓘ"/> <input type="text"/>

Presented below is an additional question to capture additional CVM submission numbers associated with a technical section incomplete letter.

Are there any additional CVM Submission Numbers associated with your CVM Technical Section Incomplete Letter(s)?

Yes
 No

Please press the ADD (+) button below to enter the CVM Submission Number(s) associated with your CVM Technical Section Incomplete Letter(s):

0 of 10 items in the list

B. Product Description

The Product Description section supports the collection of one or more product descriptions. Select the “Add” option to include a product description.

The section first collects the USP Monograph, Product Established Name, and Proprietary Name. The Proprietary Name supports special symbols, allowing for a trademark to be included.

Does the drug product have a USP monograph?

Yes
 No

Product Established Name:

Proprietary Name (make sure that the entire proprietary name is entered including trademark symbols):

Next, the Dosage Form is collected.

Select the Dosage Form:

If the Dosage Form selected supports Dosage Form Variations, then the Dosage Form Variation is presented for selection.

Select the Dosage Form:

Capsule

Select the Dosage Form Variation:

If the Dosage Form Variation selected is “Other; Unclassified”, then the option to provide additional information on the other Dosage Form Variation is presented.

▶ Select the Dosage Form Variation: ⓘ ⚠

Other; Unclassified ▼

- If Other; Unclassified is selected, please specify dosage form and variation: ⓘ

If the Dosage Form selected is “Other; Unclassified”, then the option to provide additional information on the other Dosage Form is presented.

Select the Dosage Form: ⓘ ⚠

Other; Unclassified ▼

▶ If Other; Unclassified is selected, please specify dosage form and variation: ⓘ

Next, the Route of Administration is collected.

Select the Route of Administration: ⓘ ⚠

If the Route of Administration selected supports Route of Administration Variations, then the Route of Administration Variation is presented for selection.

Select the Route of Administration: ⓘ ⚠

Oral ▼

▶ Select the Route of Administration Variation: ⓘ ⚠

If the Route of Administration Variation selected is “Other; Unclassified”, then the option to provide additional information on the other Route of Administration Variation is presented.

▶ Select the Route of Administration Variation: ⓘ ⚠

Other; Unclassified ▼

- If Other; Unclassified is selected, please specify route of administration and variation: ⓘ

If the Route of Administration selected is “Other; Unclassified”, then the option to provide additional information on the other Route of Administration is presented.

Select the Route of Administration: ⓘ ⚠

Other; Unclassified ▼

▶ If Other; Unclassified is selected, please specify route of administration and variation: ⓘ

Next, the Common Animal Name is collected.

Select the Common Animal Name:

If the Common Animal Name selected supports Class, then the Class is presented for selection.

Select the Common Animal Name:

▶ Select the Class:

If the Class selected supports Sub-Class, then the Sub-Class is presented for selection.

▶ Select the Class:

Beef Cattle

- Select the Sub-Class (if applicable):

If the Common Animal Name selected is "Other; Unclassified", then the option to provide additional information on the other Common Animal Name is presented.

Select the Common Animal Name:


▶ If Other; Unclassified is selected, please specify:

Lastly, the Proposed Indications for Use, Proposed Marketing Status, and question associated with MUMS designation status are collected.

Proposed Indication(s) for use:

Proposed Marketing Status

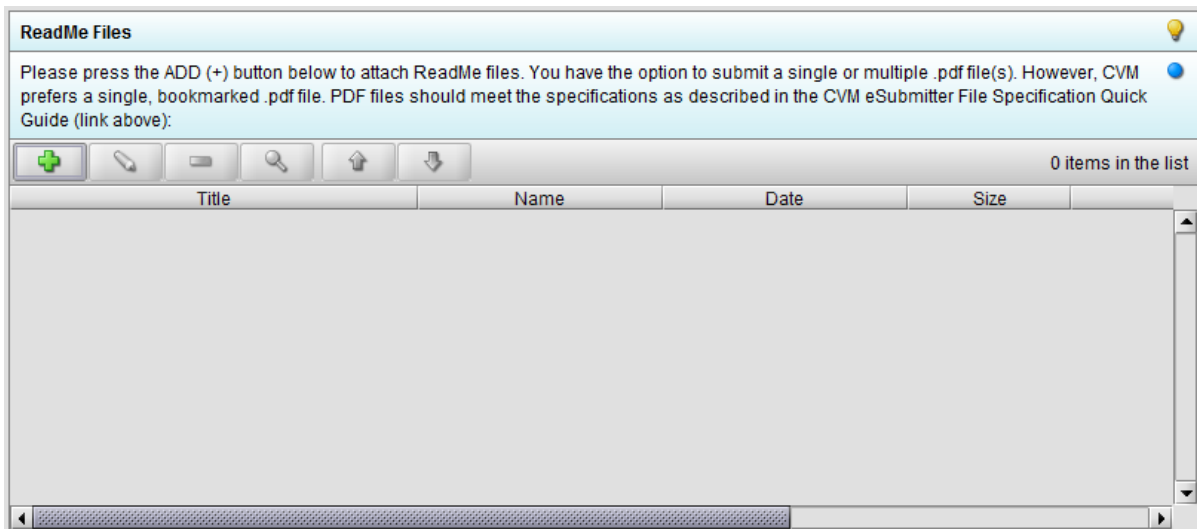
- Prescription (Rx) (section 503(f)(1) of FDCA)
- Over-the-Counter (OTC) (section 502(f)(1) of FDCA)
- Veterinary Feed Directive (section 504 of FDCA)

Has this new animal drug been formally granted minor use/minor species (MUMS) designation status for the indication proposed in the submission? 

- Yes
- No

- **List of Data Files:** In this section, you should provide a table listing the electronic data files submitted in XML or XPT file format with brief descriptions. This table should include the file name, a brief description of contents, name of data collection form if applicable, and information on how the data were collected or any reference to location of information in the FSR that is needed to interpret the data.
- **Data File Contents:** In this section, you should provide a table for each data file that includes the variable names, the abbreviations used in the file, variable label or description, formulas for derived variables, and additional details (e.g., description of coded values, unit of measure, formatting information), if applicable. Results from the CONTENTS procedure in SAS are not sufficient. If values were computed, derived, or transformed from other variables, the equation(s) for each variable and a table of the calculated values should be in the FSR.
- **Audit Trail File Listing:** In this section, if applicable, you are submitting the electronic audit trail separately from the data files for review and statistical analysis, you should provide a table listing the audit trail files submitted. This table should include the file name and the description of the file including EDC system name. For each audit trail file submitted, you should provide a table that includes the variable names, variable label or description (e.g., description of coded values, unit of measure, formatting information), and other information necessary for review.
- **Program File Listing:** In this section, you should provide a table listing the programs used to perform randomization, process the data, generate summaries, and perform the statistical analysis. This table should include the file name, the purpose of the program, the electronic data files accessed and generated by each program, and a list of any results (tables/ graphs) generated, if applicable.

You should describe the sequence of program calls needed for CVM to run your programs. Starting with the first program to be run, you should describe calls to other programs, custom functions, and macros, if any.




C.7 Data Files

The Data Files section supports the collection of data files used within the specified study. Select the “Add” option to include a set of data files for each EDC system used.

The first option is to select if an EDC system was used. If yes, then an option is provided to select the relevant EDC system from a list of EDC systems provided within the previously entered EDC systems section. If an EDC system was not used, an option is provided to briefly describe how the data was collected.

If an EDC system was selected, then additional questions will be presented related to Audit Trail Files.


Data files are to be organized according to the EDC system used to collect the information. Each EDC system referenced in section 3.5.1 “Electronic Data Capture (EDC) Systems” should be identified within this section with all associated data files. If data was collected without the use of an EDC system, then briefly describe how the data was collected.

Was an EDC system used to collect the information for the data files to be included below? ●

Yes

No







▶ Select the Associated EDC System: 💡

▶ Briefly describe how the data was collected when not using an EDC system::

Next, data files associated with the specified study and EDC information are to be included.

Data Files ●

Please press the ADD (+) button below to attach copies of data files. You have the option to submit a single or multiple eXtensible Markup Language (.xml), SAS System XPORT (.xpt), or .pdf files.

0 items in the list

Title	Name	Date	Size
(Empty table area)			

The following Audit Trail File question is presented related to a selected EDC system.

Audit Trail Files 💡

Do audit trail files exists outside the data files? ●


Yes

No







When audit trail files are submitted, the expectation is that a table will be presented that includes the variable names, variable label or description (e.g., description of coded values, unit of measure, formatting information), and other information necessary for review. At a minimum, each audit trail file should include the original and updated values of each data point, operator identification and date and time stamps for each data entry and any change, and reason for each change. Additional columns may be added as needed.

If audit trail files are included outside the data files, additional questions are provided related to the inclusion of the audit trail files.

Presented below is an option to identify if non-proprietary XML or XPT audit trail files are available.

Audit Trail Files	
Do audit trail files exist outside the data files?	
<input checked="" type="radio"/> Yes <input type="radio"/> No	
 When possible, a single electronic data file should be submitted that includes the recorded data and audit trail (non-proprietary XML or XPT file format) from the study. However, if the audit trail information can only be submitted in a separate file, that information should be submitted as an electronic data file (non-proprietary XML or XPT file format).	
▶ Do you have non-proprietary XML or XPT file format audit trail files to attach?	
<input type="radio"/> Yes <input type="radio"/> No	

Presented below is an option to attach non-proprietary XML or XPT audit trail files, when available.

▶ Do you have non-proprietary XML or XPT file format audit trail files to attach?									
<input checked="" type="radio"/> Yes <input type="radio"/> No									
- Press the ADD (+) button below to attach audit trail files. You have the option to submit a single or multiple eXtensible Markup Language (.xml) or SAS System XPORT (.xpt) files:									
<div style="border: 1px solid #ccc; padding: 5px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <div>       </div> <div style="text-align: right;">0 items in the list</div> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Title</th> <th style="width: 30%;">Name</th> <th style="width: 20%;">Date</th> <th style="width: 20%;">Size</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="height: 40px;"> </td> </tr> </tbody> </table> </div>		Title	Name	Date	Size				
Title	Name	Date	Size						

Presented below is an option to specify if audit trail files are available in PDF format.

▶ Do you have non-proprietary XML or XPT file format audit trail files to attach?	
<input type="radio"/> Yes <input checked="" type="radio"/> No	
- Do you have audit trail information that can be provided in PDF format?	
<input type="radio"/> Yes <input type="radio"/> No	

Presented below is an option to attach PDF audit trail files, when available.

●
 Do you have audit trail information that can be provided in PDF format?

Yes
 No

- Press the ADD (+) button below to attach audit trail files. You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

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Presented below is an option to describe why audit trail information is not available in either non-proprietary XML or XPT, or PDF formats.

●
 Do you have audit trail information that can be provided in PDF format?

Yes
 No

- Describe the reason(s) why the audit trail information from the electronically collected data cannot be submitted to CVM either in non-proprietary XML, XPT, or PDF file formats. A PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

C.8 Program Files

The Program Files section allows for the attachment of program files for the specified study.

For each program, document all directories and files referenced to access or store data, including directory and file names, locations, and aliases if used. Describe programs defining custom styles or formats or, if such styles or formats are predefined, provide instructions for their installation. If the programs were designed to call other programs or access data in specific folders or directory structures, describe this structure so that CVM can verify your analysis process.

Describe the sequence of program calls needed for CVM to run your programs. Starting with the first program to be run, describe calls to other programs, custom functions, and macros, if any.

Program Files

Please press the ADD (+) button below to attach program files. You have the option to submit a single or multiple eXtensible Markup Language (.xml) files.

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Title	Name	Date	Size
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C.9 Analytical Reports

The Analytical Reports section allows for the attachment of analytical reports for the specified study.

Analytical Reports

Please press the ADD (+) button below to attach analytical report files. You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide ([link above](#)):

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Title	Name	Date	Size
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C.10 Records of Communication

The Records of Communication section allows for the attachment of files in support of records of communication information for the specified study.

Records of Communication

Do you have any records of communication? ●

Yes
 No

▶ Please press the ADD (+) button below to attach records of communication files. You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above): ●

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C.11 Contributing Scientist Reports

The Contributing Scientist Reports section allows for the attachment of files in support of contributing scientist reports information for the specified study.

Contributing Scientist Reports

Do you have any contributing scientist reports? ●

Yes
 No

▶ Please press the ADD (+) button below to attach contributing scientist report files. You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above): ●

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C.12 Other Study Related Information

The Other Study Related Information section allows for the attachment of files in support of other study related information for the specified study.

Other Study Related Information

Please press the ADD (+) button below to attach other study related information files. You have the option to submit a single or multiple eXtensible Markup Language (.xml) or pdf file(s). PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

0 items in the list

Title	Name	Date	Size

D. Labeling, Freedom of Information (FOI), Further Information

The Labeling, Freedom of information (FOI), and Further Information section allows for the attachment of files in support of the following information for the submission.

Presented below is an option to attach labeling text information files, when available.

Are you submitting Labeling Text Information? ●

Yes

No

▶ Please press the ADD (+) button below to attach the Labeling Text Information relevant to this technical section. You have the option ● to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

0 items in the list

Title	Name	Date	Size

Presented below is an option to attach FOI summary information files, when available.

Are you submitting Freedom of Information (FOI) Summary Text? ●

Yes
 No

▶ Please press the ADD (+) button below to attach the Freedom of Information (FOI) Summary Text relevant to this technical section. ●
You have the option to submit a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

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Presented below is an option to attach further information files, when available.

Click 'Yes' to submit any further information related to the technical section? ●

Yes
 No

▶ Please press the ADD (+) button below to attach any further information related to the technical section. You have the option to submit ●
a single or multiple .pdf file(s). However, CVM prefers a single, bookmarked .pdf file. PDF files should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

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E. Comments

The Comments section allows for the attachment of a single file or text in support of the submission.

If you have additional comments that you would like to include in this submission, enter below or press the ADD (+) button to attach a single PDF file that contains the information. The PDF file should meet the specifications as described in the CVM eSubmitter File Specification Quick Guide (link above):

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📄

File Attachment
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