OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

FORMAT AND STYLE CONVENTIONS FOR REVIEWS AND SUBMISSION SUMMARIES

I. PURPOSE

This document:

- establishes basic style and format conventions for reviews and submission summaries associated with a Submission Tracking and Reporting System (STARS) submission,[1] and
- provides general information on the content of reviews and submission summaries.

II. SCOPE

ONADE personnel are responsible for preparing their reviews or stand-alone submission summaries using the office templates. When you prepare a review, stand-alone submission summary, or a memo to file (MTF), prepare an electronic document for the file. If the review document pertains to multiple submissions within a single administrative file (e.g., investigational new animal drug (INAD) file, new animal drug application (NADA)) or if the review document pertains to multiple administrative files, you may write a single review to cover all submissions. When closing the submissions out in Appian, upload an electronic file for each administrative file unless the submissions are linked in STARS (see P&P 1243.3030 for more information). See standard operating procedure 1243.000.007 for information on grammar standards for final action packages that undergo a quality control review by the Quality Assurance Team. These documents should adhere to the following format and style conventions.

A. Margins

The document should have a 1-inch margin on all sides of the page. Tables may extend beyond these margins for readability.

B. Fonts

- To insert a symbol, select the Insert ribbon in Word and select Symbol dropdown. In our documentation, the standard format for the trademark (™), copyright (©), and registered trademark (®) symbols is superscript. When inserting the

[1] If the final action for a submission is File No Reply (FNR), do not prepare review documentation (review or stand-alone submission summary). If the final action is FNR w/memo, prepare appropriate review documentation. The ONADE review template may be used and/or modified as needed to accommodate memos to the file.

registered trademark or copyright symbol, it must be manually superscripted to have it in the correct format. Ensure the font is 11-point Arial font when you insert Greek letters and other characters and symbols. It is at the discretion of the reviewer to either use the appropriate trademark/copyright symbol, including the proper formatting of the symbol, throughout the internal review documentation being prepared or to use the appropriate trademark symbol the first time the proprietary name is used in the review and not repeat use of the symbol throughout the remainder of the document.

- Statistical equations and similar situations should be added to documents as an image file with appropriate alternative text.

- Do not embed fonts used in the document. See P&P 1243.3005 for instruction on how to ensure fonts are not embedded.

C. 508 Compliance

Review and Submission summary documents should be created in a manner that conforms to Section 508 of the Rehabilitation Act.

D. "Clean" Electronic Files

Critically examine the electronic file of the review document(s) to remove all traces of information that are not part of the body of the file (i.e., track changes). All electronic files should be "clean" (see P&P 1243.3005).

E. Submission Descriptor Block

1. The submission descriptor block on the first page is right justified.

2. The principal submission identifier field is the first line in the submission descriptor block and is in bold type. Typically, this field identifies all principal submission(s) included in the review or submission summary. However, it is possible for a reviewer to have only an amendment assigned to them as a consult request in STARS, and not the parent submission. In those instances, it is appropriate to identify the document type and the identification of the amendment in the first line of the descriptor block.

   The principal submission identifier consists of the one uppercase letter designation of the document type, the 6-digit document number, the one uppercase letter designation of the submission or amendment type, the 4-digit submission number and the 2-letter subclass code (except for amendments), separated by dashes. Immediately following the subclass code, add the package ID in parentheses (e.g., N-012345-C-0123-CP (AA) for a primary review, N-012345-C-0123-CP (A1) for a consulting review, or N-012345-T-0123 (A1) for a consulting review of an amendment only).

   If the review applies to a group of principal submissions, include identification of all principal submissions in this field. The display order of multiple principal submissions is determined by sequentially alphabetizing by document type, placing in numerical order by document number within document type, and, if necessary, placing in numerical order by submission number within a document.

- If the multiple submissions include linked submissions, then display the lead submission (that is identified by an L in STARS) first, regardless of document type, document number, or submission number followed by the linked submissions (identified with an asterisk in STARS) using the display order described above. See P&P 1243.3030 for a definition of linked submissions and the administrative process to be followed.

- For a review that addresses two principal submissions, list the submissions on consecutive lines using the display order indicated above.

- If the review addresses multiple principal submissions, you may find it helpful to display this information in a multi-row multi-column table. This table should contain columns of equal width spanning the text area (6.25"). You should fill the table cells using the display order in a "top to bottom" order within a column and "left to right" by columns. Set the format of the table borders to "None".[2] Right-justify the table cell contents. See Appendix 1 for examples.

3. Include the target animal species and class description for the relevant project below the proprietary or established name.[3] This is not required for manufacturing or toxicology reviews. If the species or class description is exceedingly long, abbreviate this information. Provide a complete description of the species and class in the review. For example, for a rodent study to support Human Food Safety for a lactating dairy cattle product, lactating dairy cattle would be the species and class description.

4. Include sponsor's complete name. This is the name of the sponsor, not a U.S. agent or company representative. If there is any doubt regarding the appropriate name, check the name associated with the application in STARS (in the Overview screen), or for submissions made via eSubmitter, use the "Establishment Name" from the "Firm Information" section of the submission. Do not include the sponsor's address in the submission identifier information for a review or submission summary.

5. The date in the descriptor information is the date the review was completed in final and is considered the official date of the review for reference purposes. This date may differ from the date found in the electronic signature page.

F. Review Title

The title of the review reflects the type of review. Format the title so that it is centered, bolded, and in all caps. Optionally, you may also include the submission's STARS received date and a secondary title beneath the main title if it adds to the clarity or completeness of the administrative file. For example:

[2] To set the table borders to "None" in Word, select the table (by dragging to highlight the table, clicking in the table and then on the "table square" near the top left of the table, or clicking in the table and then clicking (in succession) "Table" on the "Tools" menu, "Select" from the drop-down menu, and then "Table" in the secondary menu). Once the table is selected, click "Format" on the "Tools" menu, click "Borders and shading" from the drop-down menu, click the "Borders" tab, click the "None" setting, and accept the command by clicking the "OK" button or pressing the "Return" key.

[3] Relevant project applies to all file types (i.e., NADA, INAD, JINAD, ANADA, GC, VMF).

RESIDUE CHEMISTRY REVIEW

(Submission received date e.g., June 1, 2003)

Assessment of the drug formulation components

If you are writing a stand-alone submission summary for the principal submission, title it "**SUBMISSION SUMMARY**."

G. Document Header Information

Reviews or stand-alone submission summaries exceeding one page in length have a right-justified two-line header beginning 0.5 inches from the top paper edge.[4] The header consists of the principal submission identifier (e.g., I-012345-P-0123-MC (AA)) on the first line and the review title or submission summary and a "Page x" entry on the second line (e.g., Residue Chemistry Review, Page x). The header should be visible on the second and subsequent pages. Add your package ID in parentheses immediately following the principal submission identifier (see Section C.2 above). The document header does not include information for amendments.

If the review addresses two principal submissions from one administrative file or one submission from each of two administrative files, use two lines to identify the principal submissions. Example (Principal Submission Review):

I-012345-P-0100-NV (AA)
I-013001-P-0004-NV (AA)
Environmental Review, Page 2

If the review addresses three or more principal submissions, identify only the first submission listed in the principal submission identifier field followed by the phrase "et al." to indicate the additional submissions. Example:

N-012345-C-0100-CP (B1), et al.
Residue Chemistry Review, Page 2

H. Signature Block

The signature block contains the author's name and degrees held, title, review team or division if not affiliated with a team, mail code, and office. Indent the signature block 3 inches from the left margin. Your electronic signature represents an acknowledgement that you assume responsibility as the author of the document and that the document is complete and accurate to the best of your knowledge and ability. Example:

{*see appended electronic signature page*}
Joan Smith, M.S.
Biologist
Chemotherapeutics Team, HFV-143
Office of New Animal Drug Evaluation

[4] Format the header by clicking on "Page Setup" from the "File" menu of Microsoft Word, selecting the "Layout" tab, checking the "Different first page" box, and setting the "Header" to 0.5 inches from the edge.

I. Appendices

Occasionally, additional information such as emails or journal articles may need to be included in a review document. Place this information at the end of the review document after the signature block in the template. If there is more than one item, include each document as a separate, numbered appendix.

III. PREPARING THE REVIEW DOCUMENT

In your review, include a summary of the submission content, your evaluation of the information, and your conclusions. Clearly document what letter or correspondence is sent to the sponsor and identify all enclosures. To provide consistency between review divisions, use the Word template when writing your review. A general description of each section is presented below.

A. Submission Summary (Section I of the Template)

The submission summary is an "executive summary" of the entire submission. Briefly summarize the sponsor's requests and the administrative history of the submission(s), including any amendments received. Note whether you requested consulting reviews and describe the relevant conclusions of all reviews performed, and the final decision(s) to communicate to the sponsor in the letter. If you do not use a consulting reviewer's (CR) 'Transmit to Sponsor' section as written, provide a brief explanation in the submission summary (see P&P 1240.2110 for details on dispute resolution). Do not include a chronology or description of all previous submissions to the file or application in the submission summary.

The submission summary is part of the AA review document. In certain situations, a stand-alone submission summary is prepared instead of an AA review or in addition to the summary in the AA review. See Section IV for details.

In each consulting review, the title of this first section of the review is "Review Summary" (see template). In that section, summarize only that portion of the submission you (the CR) are reviewing and put it in context as it relates to the entire submission. It is important to identify all files or submissions used to formulate the scientific and or regulatory decision. At a minimum, this section identifies the parent submission regardless of whether the parent submission was assigned to the consulting reviewer or not. In situations where the CR is only assigned an amendment and not the parent submission, it is critical to ensure the completeness of the administrative record by identifying the parent submission in the Review Summary and clearly describing what request was received by the CR.

B. Review (Section II of the Template)

Document the submission review. Each division has flexibility to determine the specific format for this section.

C. Conclusions (Section III of the Template)

Document your conclusions with respect to the submission. Your conclusions form the basis for your recommendations described in section IV of the template.

D. Recommendations (Section IV of the Template)

Document your recommendation(s) for the STARS final action or non-final action with respect to the submission. If appropriate, indicate the type of letter to be sent and list any enclosures that will be included with the letter that will be sent to the sponsor.

E. Transmit to Sponsor (Section V of the Template)

Provide, verbatim, the reviewer comments that are to be included in the letter to the sponsor. Include only your comments in the Transmit to Sponsor section and not those of other reviewers. Also, do not include standardized language for the issuing letter in the Transmit to Sponsor section.

The letter to the sponsor will consolidate comments from all reviews and incorporate any standardized language.

IV. PREPARING A STAND-ALONE SUBMISSION SUMMARY

A reviewer will prepare a stand-alone submission summary when:

- no review is written; or
- there are complicated policy issues that occur after the review is completed but before the submission is closed out in STARS that impact the transmit to sponsor/outcome.

A supervisor prepares a stand-alone submission summary when they override a reviewer's recommendation and significantly alter the transmit to sponsor section.

Include in the stand-alone submission summary: 1) items described in Section III. A. (as appropriate); and 2) a description of circumstances surrounding the preparation of the stand-alone submission summary, such as background information, meetings and their outcomes, and agreements. If the AA review has been completed, you could potentially have a stand-alone submission summary document in addition to the submission summary in the completed AA review.

V. REFERENCES

CVM Policies and Procedures Manual

1240.2110 – Procedures for Resolving Scientific Data Disagreements within CVM

CVM Program and Procedures Manual – ONADE Reviewer's Chapter

1243.2010 – Responsibilities for Keeping and Maintaining Records

1243.3005 – Creating Clean Electronic Files

1243.3030 – Completing Final Action Packages for Submission Tracking and Reporting System (STARS) Submissions

ONADE Standard Operating Procedures

1243.000.007 – Grammar Standards for Final Action Packages that Undergo a Quality Control Review by the Quality Assurance Team

VI. VERSION HISTORY

September 4, 2007 – The information in this document was originally contained in ONADE P&P 1243.3030 (November 19, 2003 version). This P&P updates the process of preparing a review and submission summary and identifies when a stand-alone submission summary should be prepared.

March 6, 2008 – Revised to include information on how to create and name amended review documentation.

December 4, 2008 – Section II revised to identify on what color paper reviews and submission summaries are printed. Section III now includes instruction to identify in any review if a letter and any attachments are being sent to the outside party, state that the AA review prepares the submission summary, and all consulting reviews have a review summary.

April 3, 2009 – Revised to include information specific to ERA processes.

October 14, 2011 – Revised to describe processes changed by implementation of Appian and electronic close out of review documentation.

October 7, 2015 – Revised to change all margins to 1.0” and remove Appendix 2 additional instructions for submissions received prior to March 14, 2011.

November 6, 2015 – Revised to remove all references to the ERA process and to clarify the method for added equations to documents.

June 21, 2016 – Revised to current format, removed instruction to embed fonts within documents, and added information relevant to receiving a consulting review for an amendment only.

August 13, 2018 – Revised to include information how to reference linked submissions in the submission descriptor block of the review in section II. E. 2.

November 14, 2018 – Revised to include more details about the target animal species and class in the descriptor block and to clarify it is not the species or class of animal on which a study is conducted per se. It is to be the target animal and class for the relevant project for the new animal drug product. In section II. Format and Style Conventions, the section on Other Administrative Information was removed. We no longer include such information at the end of the review or submission summary.

December 27, 2019 – Revised to remove the reference to the “Other Administrative Information Box” in the template in section I. Appendices. We no longer have the administrative information box in the template.

January 26, 2021 – Updated section II. B. to clarify information about inserting and formatting symbols within our documents. It specifically states that the reviewer may decide whether to repeat the trademark symbol throughout their internal review documentation or to use the trademark symbol the first time the proprietary name is used and not repeat it throughout the remainder of the document.

July 21, 2022 – Quality systems review for minor formatting updates.

March 29, 2023 – Updated the information on standards to reflect the office switch to Arial 11-point font as our standard font. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

April 5, 2024 - Edited section III. to include reference to the SOP on grammar standards for final action packages that undergo a quality control review by the QA Team. Reviewers may choose to apply those standards to other reviews and review documentation they prepare. The document was also put into the current office format and template.

APPENDIX 1. FORMAT FOR MULTIPLE SUBMISSION IDENTIFIERS

List the submission identification information in a logical way that makes it easy for the reader to understand to which submissions the identification information pertains. For example, if the same information (e.g., proprietary and drug product established name, outside party information) pertains to multiple submissions being addressed in the same review or stand-alone submission summary, list all the principal submissions in numerical order followed by the remaining information, as shown here.

I-012345-P-0161-EF (AA)
I-012346-P-0162-EF (AA)
I-012347-P-0159-EF (AA)
I-012348-P-0054-EF (AA)
Proprietary name
(drug product established name)
Species and animal class
Sponsor's name
January 1, 2007

If the information is not the same for all the principal submissions being addressed in the review or stand-alone submission summary (e.g., if different products are involved), list the "different" information with each principal submission, followed by the information that is common to all the submissions. The example below shows how to present the information for applications with different proprietary names; they may or may not have the same established name. If there are more than three submissions, use a table, as shown here.

N-012345-C-0119-CI (AA) Proprietary name (drug product established name)	**N-012347-C-0109-CI (AA)** Proprietary name (drug product established name)	**N-012349-C-0115-CI (AA)** Proprietary name (drug product established name)
N-012346-C-0109-CI (AA) Proprietary name (drug product established name)	**N-012348-C-0115-CI (AA)** Proprietary name (drug product established name)	**N-012350-C-0110-CI (AA)** Proprietary name (drug product established name)
		N-012351-C-0033-CI (AA) Proprietary name (drug product established name)

If multiple species and/or classes are involved, it is acceptable to truncate the information (e.g., write "Cattle" instead of "Cattle: Beef, Non-lactating Dairy, and Lactating Dairy", or write "Multiple Species and Classes" instead of listing each individual species and class). Include the detailed species information in your submission summary or review summary. Species and class information is not required on reviews or stand-alone submission summaries for Chemistry, Manufacturing, and Controls submissions.