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 STARS submission,[1] and
- Provides general information regarding the content of reviews and submission summaries.

II. FORMAT AND STYLE CONVENTIONS

ONADE personnel are responsible for preparing their reviews or stand-alone submission summaries using the office templates. These documents should adhere to the format and style conventions as follows:

[1] If the final action for a submission is File No Reply (FNR), do not prepare any review documentation (review or stand-alone submission summary). If the final action is FNR w/memo, you will prepare appropriate review documentation.

A. Margins

The document should have a 1.25 inch left margin and a 1 inch margin at the right, top, and bottom of the page. Tables may extend beyond these margins for readability.

B. Fonts

- Use 12 point Times New Roman font. The 12 point Symbol font should be used to insert Greek letters and special characters.

- For statistical equations and similar situations use Microsoft Equation or the MathType plug-in for Microsoft Word.

- Embed all fonts used in the document to create a clean electronic document. See P&P 1243.3005.

C. Submission descriptor block

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

2. The principal submission identification field is the first item in the submission descriptor block and should be in bold type. This field identifies all principal submission(s) included in the review or submission summary. Amendments are not considered principal submissions and are not identified here.

   The identification of a principal submission consists of the one uppercase letter designation of the document type, the 6-digit document number, the one uppercase letter designation of the submission type, the 4-digit submission number and the 2-letter subclass code, 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 or N-012345-C-0123-CP (A1) for a consulting review).

   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. For a review that addresses two principal submissions, list the submissions on consecutive lines using the display order. 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. You should set the format of the table borders to "None".[2] You should right-justify the table cell contents. See Appendix 1 for examples.

3. Place the proprietary and established names for the finished drug product immediately below the principal submission identifier. When the proprietary and established names are both used, put the established name in parentheses. If a new animal drug does not have a proprietary name, use the established name. If it doesn't have either, use the identifier provided by the sponsor, e.g. drug class, alpha-numeric code.

4. Include the species and class description below the proprietary or established name. 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.

5. Include sponsor's complete name. This should be 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) and consult with your team leader or division director. Do not include the sponsor's address in the submission identifier information for a review or submission summary.

6. The date in the descriptor information should be the date the review was printed in final and will be considered the official date of the review for

[2] To set the table borders to "None" in Microsoft 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.

reference purposes. This date may differ from the signed date found in the signature block.

D. Review Title

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

RESIDUE CHEMISTRY REVIEW
(Submission dated June 1, 2003)
Assessment of the drug product formulation components

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

E. Document Header Information

Reviews or stand-alone submission summaries exceeding one page in length should have a right-justified two-line header beginning 0.5 inches from the top paper edge.[3] 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 should not include 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.

[3] 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.

Example:

I-012345-P-0100-NV (AA) I-013001-P-0004-NV (AA) Residue Chemistry 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

F. 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 and leave room for your signature and date above the signature block. When printed in final, sign and date your review. Your signature and date 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:

John Smith, M.S.
Biologist
Chemotherapeutics Team, HFV-143
Office of New Animal Drug Evaluation

G. cc: Block

The cc: block begins two blank lines below the last line of the signature block. If the contents of the cc: block does not fit on the same page as the signature block, insert a page break and place the cc: block at the top of the next page. The cc:

block should list all submissions being completed with the final action package, including amendments. List principal submissions on separate lines. List amendments on the same line as their principal submission.

Examples of cc: block notation:

cc: Document Control Unit, for the administrative file of: I-012345-P-0123-MC, T-0125, T-0126

cc: Document Control Unit, for the administrative files of: I-012345-P-0123-MC, T-0125, T-0126 I-012346-P-0088-MC, T-0090 I-012346-P-0089-MC I-012348-P-0007-MC, T-0008

H. Other administrative information

This area is used to record additional information such as a preparer line, notation of electronic copies, to document draft tracking and to record supervisory review, when applicable.[4] The default for this field is "not applicable." Do not delete the box or heading.

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 Other Administrative Information box in the template. If there is more than one item, include each document as a separate, numbered appendix. If possible, this information should also be included in the same electronic file as the review document. If this is not possible, include a statement in your review, which indicates that the appendix is included in the paper copy of the review only.

[4] For information regarding supervisory review of CVM work products and dispute resolution, consult P&P 1240.2110 "Procedures for Resolving Scientific/Data Disagreements Within CVM."

III. PREPARING THE REVIEW DOCUMENT

Include in your review, a summary of the submission content, your evaluation of the information, and your conclusions. 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 template)

The submission summary is an "executive summary" of the entire submission Briefly summarize the sponsor's requests, the administrative history of the submission(s), note whether consulting reviews were requested, the relevant conclusions of all reviews performed, and the final decision(s) to be communicated to the sponsor in the letter. If a consulting reviewer's transmit to sponsor is not used as written, provide a brief explanation in the submission summary.[5] 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 will be prepared instead of an AA review or in addition to the summary in the AA review. See section V for details.

In a consulting review, the title of this section will be "Review Summary" (see template). Summarize only that portion of the submission you are reviewing and put it in context as it relates to the entire submission.

B. Review (section II of template)

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

C. Conclusions (section III of template)

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

[5] If you need to document further discussion and concurrence with consulting reviewers, include this in the review section.

D. Recommendations (section IV of template)

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

E. Transmit to Sponsor (section V of 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.

- There are complicated policy issues that occur after the review is completed but before the submission is finaled out in STARS that impact the transmit to sponsor/outcome.

A supervisor will prepare 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 IV.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 and a submission summary in the completed review.

V. REFERENCES

CVM Program Policy and Procedures Manual

1243.2010 - Responsibilities for Creating and Keeping Records

1243.3030 - Completing Final Action Packages

1243.3005 - Creating Clean Electronic Documents

1243.3060 - Final Document Routing and Copy Distribution for NADAs, ANADAs, INADs, JINADs, Master Files, and Suitability Petition

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.

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 established name, and outside party information) pertains to multiple submissions being addressed in the same review or stand-alone submission summary, list all of 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
(established name)
Species and animal class
Sponsor's name
January 1, 2007

If the information is not the same for all of the principal submissions (e.g. if different products are involved) being addressed in the review or stand-alone submission summary, list the "different" information with each principal submission, followed by the information that is common to all of 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
(established name)

N-012347-C-0109-CI (AA)
Proprietary name
(established name)

N-012349-C-0115-CI (AA)
Proprietary name
(established name)

N-012346-C-0109-CI (AA)
Proprietary name
(established name)

N-012348-C-0115-CI (AA)
Proprietary name
(established name)

N-012350-C-0110-CI (AA)
Proprietary name
(established name)

N-012351-C-0033-CI (AA)
Proprietary name
(established name)

Species and animal class

Sponsor's name
January 1, 2007

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.