
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER’S CHAPTER

FORMAT AND STYLE CONVENTIONS FOR LETTERS

I. Purpose.....1
II. Standing and impact of our letters1
III. Format and style conventions.....1
IV. Writing with clarity.....6
V. “Clean” electronic files7
VI. References.....7
VII. Version history.....7

I. PURPOSE

This document establishes basic format and style conventions for letters the Office of New Animal Drug Evaluation (ONADE) issues to sponsors and other outside parties.

II. STANDING AND IMPACT OF OUR LETTERS

Our letters are part of official government records and, as such, need to ensure adequate and proper documentation of our decisions and transactions. Our letters also can have significant impacts on their recipients. Based on their understanding of our letters, sponsors may make decisions to reallocate the sponsor’s priorities, time, money, and effort to serve the needs of the company. Therefore, we should issue letters that clearly and precisely convey our decisions on particular issues.

III. FORMAT AND STYLE CONVENTIONS

A written letter is our principal and preferred form for communicating information to sponsors or other outside parties. These letters document our decisions as they relate to particular issues. Adhering to a set of format and style conventions increases the consistency in the quality and appearance of our letters.

Experts have published style manuals presenting their particular preferred format and style conventions for writing letters. These preferred styles and conventions are not entirely consistent and they do not remain static over time. The preferred set of conventions and styles we have adopted in this document consider several experts’ sets of styles and conventions, our past practices, and our need for clarity and consistency in the letters we issue. 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.

If we have developed a template for a particular type of letter, use it. If no other ONADE letter template exists, use the Acknowledgment letter template so that your letter is consistent with the styles and conventions presented in this document.

A. Copies of Letters

Prepare the electronic file for the letter. If the letter pertains to multiple submissions within a single administrative file (e.g., investigative new animal drug (INAD) file, new

animal drug application (NADA)) or if the letter pertains to multiple administrative files, you may write a single letter to cover all submissions. When closing the submission out in Appian, upload an electronic file for each administrative file unless the submissions are linked in our Submission Tracking and Reporting System (STARS) (see P&P 1243.3030).

B. Margins

Use the following margins on all letters: all margins (i.e., left, right, top, and bottom margins) should be 1 inch.

C. Fonts

Use Arial (11-point) as the principal font family. The predominant font style you should use is “regular.” You may use *italic* and **bold** styles judiciously for emphasis and clarity. You may also use other font effects such as underline, CAPITALIZATION, and SMALL CAPITALIZATION sparingly (e.g., When we use the full name of the FEDERAL REGISTER it is in small caps.). The overuse of font styles and effects can compromise clarity. Do not manually adjust the spacing between characters (i.e., kern fonts).

To insert a symbol, select the Insert ribbon in Microsoft Word and then select the Symbol dropdown. In our documentation, the standard format for the trademark (™) and registered trademark (®) symbols is superscript. When inserting the registered trademark symbol using the Symbol option, you must manually superscript it to have it in the correct format. See P&P 1243.3015 for information on the formatting and use of proprietary names in letters and documents sent to sponsors. Always use 11-point Arial font when you insert Greek letters and other characters and symbols. Use Microsoft Equation or the MathType plug-in for Microsoft Word for statistical equations and similar uses. Note: when you use Microsoft Equation or the MathType plug in, you need to tag the item as an object and give it alternative text (Alt-Text) in order for the information to be section 508 compliant. Use Arial font in equations as well.

D. 508 Compliance

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

E. Headers

Letters exceeding one page in length should have a right-justified 10-point header beginning 0.5 inches from the top paper edge. This header should be visible on the second and subsequent pages.¹ Typically, the header consists of the principal submission identification, e.g., I-012345-P-0123-EF, on the first line and a “Page x” entry on the second line. Example:

I-012345-P-0123-EF
Page 2

If the letter addresses two principal submissions from one document or one submission from each of two documents, use two lines to identify the principal submissions. Example:

¹ To format the header, click on “Page Setup” from the “File” menu of Microsoft Word, select the “Layout” tab, check the “Different first page” box, and set the “Header” to 0.5 inches from the edge.

I-012345-G-0100-OT

I-013001-G-0004-OT

Page 2

If the letter addresses three or more principal submissions, the first line should 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-012635-C-0100-OT, et al.

Page 2

Where the letter does not address a submission, the first line of the header should be the content of the reference (“Re:”) line. Example:

Reference line text here

Page 2

F. Principal Submission Identification Field

This field identifies the principal submission(s) to which this letter responds. Amending submissions, or other submissions that provide ancillary or supporting information, are not principal submissions and are not identified here. 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 type, the 4-digit submission number, and the two uppercase letter subclass code, separated by dashes.

This field is the top-most text placed on the first page. It begins at the left margin on a line that is no less than 0.75 inches below the top margin of 1 inch. When a one-page letter is brief, you can begin the letter by placing this field further down the page to “center” the letter on the page visually.

If the letter addresses an issue that applies to a group of principal submissions, include all principal submission identifiers in this field. The display order of 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 letter that addresses two principal submissions, list the submissions on consecutive lines using the display order indicated above.
- If the letter addresses three or more principal submissions, create a multi-row three-column (of equal width spanning the text area (6.25”)) table that is sufficiently large to capture all principal submissions. 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 Left-justify the table cell contents.

Examples:

I-012345-G-0011-OT
N-141141-G-0234-OT

N-100635-C-0100-OT	N-113645-C-0101-OT	N-141068-C-0052-OT
N-101314-C-0098-OT	N-123045-C-0100-OT	N-141071-C-0027-OT
N-101315-C-0097-OT	N-141013-C-0088-OT	

G. Inside Address

Direct the letter to the attention of the Responsible Official (or the U.S. agent/U.S.-based employee, if the sponsor is not a U.S. firm) who signed the Form 356v of the paper submission or as listed in the eSubmitter form. Note: When U.S. firms have a consultant or other subject matter expert make a submission on their behalf, we address the letter to the consultant (i.e., the responsible official). Use the firm name, address, and other information from the Responsible Official section (or the U.S. agent/U.S.-based employee section) to populate the inside address of the letter. However, if you find obvious typographical errors (i.e., spelling) in either the firm name, firm address, or responsible official information, use the correct information in the inside address instead of using the incorrect information from the form.

Additionally, if the firm name in the Responsible Official Information section of the eSubmitter form (or for paper submissions, in the cover letter) appears to be incorrect or is unclear regarding the identity of the drug application sponsor (e.g., if the firm name is written in the eSubmitter form or cover letter as “Drug Company Animal Health” and the firm name listed in 21 CFR 510.600 is “Drug Company Animal Health, a Division of Drug Company Inc.”), contact the responsible official to obtain the correct name. Likewise, if there is more than one responsible official involved in the submission (e.g., one responsible official made the initial submission and a different person is the responsible official for an amendment and you are not sure to whom to address the response, contact the sponsor to confirm the correct name to use. Note in your review documentation that you contacted the sponsor to clarify the information, and if applicable, make note of the corrected name in your review documentation and in the Request for QC Review form, and use the corrected name in the inside address.

You may also modify the stylistic presentation (capitalization, punctuation, and spacing) of the firm name and the official’s name, titles, and degrees contained in the form to match the addressee’s preference in the cover letter. However, do not add information (e.g., degrees) if it is not in the information provided in the Form 356v or eSubmitter form. The inside address begins two blank lines below the principal submission identification field. 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.

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

H. Reference Line

The reference line should briefly (typically 3-8 words) identify the main topic of the letter. The reference line begins one blank line below the inside address. Example:

Re: Request for review of study protocol 2005-123abc-ver3b

I. Salutation

Example:

Dear Dr. Doe:

J. Body of the Letter

Do not indent the first line of a paragraph. Each paragraph should begin at the far-left margin or, for subordinate paragraphs, at the new margin established by the subordinate position of the paragraph. You should separate paragraphs by one blank line.

1. First paragraph

The first sentence should convey our main decision regarding the issue presented in the letter(s) to which we are responding. Use the remaining sentences of this paragraph to provide the supporting and limiting information that place the main decision or action in the proper and accurate context.

2. Subsequent paragraphs

These paragraphs (if needed) should convey all other necessary information to provide a complete response for the letter to which we are responding.³ What constitutes a complete response may vary with the type and quality of the letter or submission.

3. Closing paragraph

The final paragraph politely ends the letter. Include a sentence instructing the recipient to refer to the date and the principal submission identifier found at the top of our letter when submitting correspondence relating to our letter. Identify an individual the addressee can contact for further information. If the contact is the individual who signs the letter, include their phone number and email address. If the contact is someone other than the individual who signs the letter or multiple points of contact, identify the individual(s) by name, organizational title, and provide their phone number and email address.

³ A complete response means that we have addressed the issues raised in the letter consistent with our regulations and policies.

K. Complimentary Closing and Signature Block

Use “Sincerely,” as the complimentary closing. The closing begins one blank line below the closing paragraph. The content of the signature block should conform to that established for the individual signing the letter. The first line of the signature block should begin three blank lines below the closing. Indent the closing and signature block 3 inches from the left margin. Example:

Sincerely,

{see appended electronic signature page}

Matthew A. Lucia, D.V.M.

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine

L. Enclosure Notation

Insert the enclosure notation only if additional items are included with the response to the sponsor. The enclosure information begins at the left margin two blank lines below the bottom of the signature block. The first line is “Enclosure:” (plural if more than one enclosure). The second and additional lines are brief descriptions of the enclosures (one line per enclosure).

Example:

Enclosures:

Title (or brief description) of enclosure 1

Title (or brief description) of enclosure 2

All enclosures itemized in the letter should be included in the final action package and designated as “send to firm” in Appian.

M. cc: Block Notation in Issuing Letters

Include a cc: block in an issuing letter to indicate that we are sending the letter to other parties external to FDA. For example, include a cc: block notation in food-use authorization letters for terrestrial species because USDA/FSIS gets a copy of the letter. Internal (FDA) routings of the letter are never included in the cc: block of the issuing letter. The cc: block begins at the left margin two blank lines below the bottom of the signature block. Example:

cc:

USDA/FSIS

IV. WRITING WITH CLARITY

As discussed in Section II, there are important reasons for you to prepare letters of exceptional quality and clarity. When you draft a letter, use plain language writing techniques.⁴ For example, use the active voice when possible and write at the level

⁴ See <http://www.plainlanguage.gov> and <http://www.archives.gov/federal-register/write/plain-language/>.

appropriate for your audience. Writing at a level appropriate to your audience includes remembering that they may not be as intimately versed in your area of expertise as you are, so keep the use of technical acronyms and jargon to a minimum to clearly convey your intended meaning. You may find the use of the Graham methods of pre-drafting, drafting, and editing of the letter helpful.⁵ In addition, use the spell check and grammar function of your word processor. Proofread the letter to catch any errors that automated spell checking, and grammar tests may not identify.

V. “CLEAN” ELECTRONIC FILES

Critically examine the electronic file of the letter to remove all traces of information that are not part of the body of the file. All electronic files should be “clean” (see P&P 1243.3005).

VI. REFERENCES

Books

Graham, D.O. and J.H. Graham. 2002. *The Writing System: A step-by-step guide for business and technical writers*, Preview Press, Fairfax, VA.

Plain language web sites

<http://www.plainlanguage.gov>

<http://www.archives.gov/federal-register/write/plain-language/>

CVM Policies and Procedures Manual

1240.2110 – Procedures for Resolving Scientific Data Disagreements within CVM

CVM Policies and Procedures Manual – ONADE Reviewer’s Chapter

1243.3005 - Creating Clean Electronic Files

1243.3015 – Proprietary Names

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

VII. VERSION HISTORY

May 24, 2005 – original version

July 1, 2005 – minor changes to content of concurrence table (section III. L. 3.)

⁵ See Graham, D.O. and J.H. Graham, 2002, *The Writing System: A Step-by-Step Guide for Business and Technical Writers*, Preview Press, Fairfax, VA. If you have questions or need help with the procedures, contact the Quality Assurance Team.

September 4, 2007 – Changed to add subclass code to the submission identifier and replace the preparer line with the Other Administrative Information box. Also referencing the new P&P 1243.3005.

December 4, 2008 – Revised to clarify that the file copy of all letters and the file copies of enclosures accompanying the letter are printed on pink paper. Removed reference to 1243.3060 Final document routing and copy distribution, which no longer exists.

October 14, 2011 – Revised to describe processes changed by implementation of Appian and how to final out review documentation electronically.

October 7, 2015 - Revised to change all margins to 1.0” and remove Appendix 1 additional instructions for submissions received prior to March 14, 2011.

June 13, 2016 – Revised to current format, removed instruction to embed fonts, and removed mention of submissions made prior to March 14, 2011.

March 9, 2018 – Revised to clarify procedures regarding the inside address of the letter.

August 1, 2018 – Revised Section III. F. to include instructions on how to reference linked submissions. Also, updated information in the section on closing paragraphs to instruct the preparer of the letter to include the email address of the point of contact(s) identified in the closing paragraph.

January 26, 2021 – Updated section III. C. to clarify information about inserting and formatting symbols within our documents.

July 16, 2021 – Updated the inside address section to clarify that when there is a U.S. Agent, the letter is addressed to them and the Sponsor name is not included in the address block.

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

December 8, 2022 - Section III. G. was updated to include information on what to do when more than one responsible official is involved in a sponsor’s submission.

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 Arial11-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 letters they prepare. Edited section III. G. to clarify to clarify that a U.S. firm may have consultants make submissions on the firm’s behalf. In that case, we will send our response letter to that consultant as they are the responsible official for the submission. The document was also put into the current template and format for the office and minor grammatical corrections made.