
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

FORMAT AND STYLE CONVENTIONS FOR LETTERS

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I. PURPOSE

This document establishes basic format and style conventions for letters the Office of New Animal Drug Evaluation (we) 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, nor do they 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.

If we have developed a template for a particular type of letter, you should use it.¹ If we have not developed one, you should draft your letter consistent with the styles and conventions presented in this document.

A. Paper copies of letters

1. Issuing letter

The issuing letter is the signed copy of the letter that we send to the addressee, i.e., the sponsor or other outside party.

As the preparer of the letter, you should print the first page of a letter on department (Department of Health and Human Services) letterhead paper, i.e., watermarked bond paper displaying the department's official pre-printed blue letterhead logo.² You should print the remaining pages of a letter on quality watermarked bond paper.

2. File copy

The file copy of the letter is the paper copy of the letter that we print on plain (i.e., without department letterhead) pink paper and place in the administrative file.³ The use of pink paper helps us find this letter in the administrative file.

¹ The Office's goal is to develop templates that adhere to these format and style conventions as well as provide some flexibility to address division needs. If you find that the template is not consistent with these conventions or will not adequately convey the information necessary, you should discuss the need for revising the current template with your division director (or staff leader). If a revision is necessary, you and your division director should discuss the proposed revision with the ONADE Policy Team. They will evaluate whether the proposed revision is necessary or another alternative action is preferable.

² Do not use computer-created facsimiles of the letterhead logo for the letter.

³ Examples of administrative files for STARS submissions include generic investigational new animal drug files (JINADs), new animal drug application (NADAs), or veterinary master file (VMFs).

We keep these paper administrative files in our records archive (the Document Control Unit).

B. Margins

You should use the following margins on all letters: left margin of 1.25 inches; right, top, and bottom margins of 1 inch.

C. Fonts

You should use Times New Roman (12 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. The overuse of font styles and effects can compromise clarity. You should not manually adjust the spacing between characters (i.e., kern fonts).

If writing the proprietary name, do not use trademark symbols (® or ™). To identify the proprietary name, refer to the proprietary name box on the most recently submitted Form 356V, if applicable. Write the portion of proprietary name to the left of the trademark symbol in ALL CAPS in our documents. If the proprietary name contains words to the right of the trademark symbol, capitalize the first letter of each word (e.g., Program® Injectable Solution would be PROGRAM Injectable Solution). For proprietary names that are not trademarked, capitalize the first letter of each word.

When you need to use Greek, and similar, characters, you should insert them using the Symbol font (12 point). You should use Microsoft Equation or the MathType plug-in for Microsoft Word for statistical equations and similar uses.

You should embed all fonts used in the letter in the electronic file of the letter. See P&P 1243.3005

D. Headers

Letters exceeding one page in length should have a right-justified 12-point header beginning 0.5 inches from the top paper edge. This header should be visible on the

second and subsequent pages.⁴ 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:

I-012345-G-0100-OT I-013001-G-0004-OT Page 2
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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

⁴ 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.

E. 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 considered principal submissions and thus are not identified here.⁵ 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 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 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 letter that addresses two principal submissions, list the submissions on consecutive lines using the display order. 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. 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”.⁶ You should left-justify the table cell contents.

⁵ See section III.L.1 for how these amending and other ancillary submissions are identified in the cc: block.

⁶ 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.

Examples:

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

F. Inside address

Direct the letter to the attention of whoever signed the cover letter of the submission. Use the address of the cover letter accompanying the application.⁷

In situations where the sponsor is not the company identified in the letterhead, identify the sponsor by name in the opening paragraph of the letter.⁸ If the address or contact information has changed since the application was received, document this change in a memorandum to the file or your review and use the new information for the letter.

You should follow the addressee's preference in the spelling, capitalization, punctuation and spacing of his or her name and title as evident from the letter received. Likewise, follow the indicated preference for the company's name and address. The inside address begins two blank lines below the principal submission identification field.

Example:

Drug Company International Attention: John Doe, DVM, PhD Manager, Regulatory Affairs
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⁷ With the exception of master files, address all communications with a foreign sponsor to their U.S. agent.

⁸ Examples of when a letter or submission may not be sent to us directly by the sponsor and may be sent by another party on the sponsor's behalf: 1) the company is not a United States company, they will have U.S. Agent; 2) correspondence may come from consultants; 3) a parent company submits information on a subsidiary's behalf.

1100 Industrial Drive, Suite 500
Anytown, NJ 55555

G. 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

H. Salutation

You should look to the signature block of the submission to help identify the most appropriate title of the individual to whom the letter is addressed. The salutation of our letter should respect titles conferred by professional degree. You should abbreviate most titles (e.g., Mr., Mrs., Ms., and Dr.) and use only the surname. The salutation should begin one blank line below the reference line.

Example:

Dear Dr. Doe:

I. Body of letter

You should 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. You should 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.⁹ 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. You should include a sentence instructing the recipient to refer to the date and the principal submission identification field found at the top of our letter when submitting correspondence relating to our letter. You should also identify an individual the addressee can contact for further information. If the contact is the individual who signs the letter, you should include his or her telephone number. If the contact is someone other than the individual who signs the letter, you should identify that individual by name, organizational title, and telephone number.

J. Complimentary closing and signature block

You should 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.

You should indent the closing and signature block 3 inches from the left margin.

⁹ A complete response means that we have addressed the issues raised in the letter consistent with our regulations and policies.

Example:

Sincerely,
Steven D. Vaughn, DVM Director Office of New Animal Drug Evaluation

K. Enclosure notation

You should insert this notation only if additional items are included in the envelope with the letter. 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).

All enclosures itemized in the letter should be included behind the letter in the order mentioned. You should print (or photocopy as necessary) the enclosures on good quality plain (no watermark) white paper. You should individually staple the enclosures, if necessary.

Example:

Enclosures: Title (or brief description) of enclosure 1 Title (or brief description) of enclosure 2

L. Internal administrative tools

We use several administrative tools (cc: blocks, concurrence tables, and the other administrative information box) to document the internal processing and clearance of our letters. All of this administrative information should always appear on our file (pink) copy of the letter. Issuing letters should never include internal routing and clearance information and only in rare situations (see below) contain a cc: block.

1. cc: block notation

The cc: block begins two blank lines below the last line of the signature block, or enclosure notation (if present).

You should not include a cc: block in an issuing letter except to indicate that we are sending the letter to other parties external to FDA. Internal (FDA) routings of the letter are never included in the cc: block of the issuing letter.

In contrast to the identification of only principal submissions in the header and the principal submission identification field, the cc: block on the file (pink) copy should list all submissions being completed with the final action package. The submissions of each document should be on a single line.

As a matter of routine, we should not create paper copies of the issuing letter for CVM personnel nor include them in the cc: list. Interested CVM individuals can find copies of these letters in our electronic archive. In those instances where paper copies of the letter are necessary for use outside of CVM (but within FDA), you should note these copies in the cc: block of the file (pink) copy.

Examples of cc: block notation for a file (pink) copy:

cc: Document Control Unit, for the administrative file of: I-012345-P-0123-EF, T-0125, T-0126
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cc: Document Control Unit, for the administrative files of: I-012345-P-0123-EF, T-0125, T-0126 I-012875-G-0088-OT, T-0090 I-012903-G-0045-OT, T-0046 I-013004-G-0007-OT, T-0008

cc: Document Control Unit, for the administrative file of: I-012345-D-0123-OT, T-0125, T-0126 USDA/FSIS

Note that the issuing letter of the last example would include a cc: notation:

cc: USDA/FSIS

2. Concurrence table

The purpose of the concurrence table is to provide a standardized method and place to indicate review of, and concurrence with, the letter. The table should indicate all participants (except the signer of the letter) in the review and clearance process for the letter beginning with the primary reviewer. The exact participants identified in the table will vary with the type of letter and the review group responsible for its review. The signer of the letter indicates concurrence by signing the letter. The table should identify each individual by role and organizational unit. For most issuing letters, you only need to indicate concurrence with the final letter. However, for a few letters, most notably approval letters, you should indicate concurrence on the draft and final letter.

Example:

Concurrence	Signature & Date
individual name, Primary Reviewer, team name	
individual name, Leader, team name	
[if appropriate, insert information regarding specialty team/division personnel: individual name, title, and team name]	
template version- date	

3. 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 applicable¹⁰. The default for this field is “not applicable.” Do not delete the box or heading.

M. Envelope

The envelope accompanying the letter should:

- Be appropriately sized for the material being sent,
- Be pre-printed with the department’s return address,
- Be addressed to match the inside address of the letter, and
- Have the Document Control Unit (DCU) mail code (HFV-199), added by hand or printer, above the return address of the envelope to allow proper return of the letter if the postal service is unable to deliver it.

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, you should use plain language writing techniques.¹¹ For example, use the active voice when possible and write at the level 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 you should keep the use of technical acronyms and jargon to a minimum to clearly convey your intended meaning. You may also find the use of the Graham methods of pre-drafting, drafting and editing of the letter helpful.¹² In addition, use the spell check and grammar function of your word processor. You should proofread the letter to catch any errors that automated spell checking and grammar tests may not identify.

¹⁰ 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.”

¹¹ See <http://www.plainlanguage.gov> and http://www.archives.gov/federal_register/plain_language/tools.html.

¹² 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 writer/editor from the Quality Assurance Team.

V. “CLEAN” ELECTRONIC FILES

You should 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” and identical to the printed version.¹³

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/plain_language/tools.html

CVM Program Policy and Procedures Manual

1243.3005 - Creating Clean Electronic Files

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

VII. VERSION HISTORY

May 24, 2005 – original version

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

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.

¹³ See P&P 1243.3005 on how to create clean electronic files