
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

CLOSING OUT CONSULTING REVIEWS FOR STARS SUBMISSIONS

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I. PURPOSE

This document describes the information to submit to the Document Control Unit (DCU), or requesting reviewer, to close out a consulting review for any Submission

II. CONSULTING REVIEWS

Some submissions are complex and require review by additional individuals with expertise in different scientific disciplines. These individuals are called consulting reviewers for the submission and the review they produce is called a consulting review.

Where the review of a submission requires one or more consulting reviews, the primary review division should request these reviews through STARS within five days after the submission is date-stamped by the DCU. Prompt requests for consulting reviews will ensure that the consulting review division has sufficient time to perform the review.

There may be more than one level of consulting reviews in ONADE. An "A1" consulting review refers to a consulting review for a submission requested through STARS directly by the primary review division. Multiple consulting review requests from the primary review division are sequentially identified using "A1", "B1", etc. An "A2" consulting review refers to a consulting review for a submission requested through STARS by a reviewer already consulted on the submission (a request for a

consult from an “A1” consulting reviewer). Additional consulting reviews of the “A2” submission would have sequential numbers (for example, “A3”, “A4”, and so on).

III. ENSURING THE ACCURACY OF STARS

Before returning the consulting review package, confirm the accuracy of the information on the DCU Routing Slip (Review Request and Movement Form) forwarded with the submission(s). If you have any comments or specific questions regarding the STARS information for a submission, contact the primary review division to discuss potential corrections. Addressing these potential issues early during the review period will minimize related problems during the return of your review.

IV. RETURNING THE SUBMISSION(S) TO THE DCU

The consulting review division personnel are responsible for reviewing the information contained in the submission, preparing review document(s) consistent with P&P 1243.3009 on format and content for reviews, printing them on yellow paper, and returning the review document(s) through STARS to the requesting division.¹ Prepare only one copy of your review for the file and print it on yellow paper. Also print one copy of any attachments accompanying the review, even those that are intended to go to the sponsor (e.g., finding of no significant impact a.k.a. FONSI), on yellow paper. The primary reviewer of the submission or their designee will make the necessary white and pink photocopies of attachments intended to be enclosed with the letter for the final action package. You are also responsible for returning all materials provided to you, including desk copies, when you close out the submission.²

V. RESPONSIBILITIES FOR CLOSING OUT THE CONSULTING REVIEWS

After completing their review, consulting review division personnel should assemble all the paper review documentation and their electronic counterparts. If the review document pertains to multiple submissions within a single administrative file (i.e.,

¹ Not all requests for a consulting review will result in the preparation of review documents by the consulting reviewer. The use of yellow paper for review documents facilitates the easy identification of CVM-created records in the administrative file for later reference.

² A desk copy is an additional copy of all or part of the submission submitted by the sponsor directly to review personnel. All materials submitted to review personnel should be logged through STARS. Sponsors should be discouraged from submitting desk copies to review personnel.

INAD file, NADA file, etc.), provide a single electronic file for the administrative file. If the review document pertains to multiple administrative files, provide an electronic file for each administrative file.³ All electronic files should be “clean” and identical to the printed version.⁴ If you requested a consulting review (for example an “A2” consult), also include all paper copies of that review documentation beneath your review.

Some consulting review requests will not result in a written consulting review document. In these cases, note that there is no review documentation in the comments box of the Review Request and Movement Form for paper submissions or in the comment window in Outlook Notification Form Integration (ONFI) for electronic submissions.⁵ Return all materials provided with the request for the consult to the requesting division through the DCU.

The following steps, for consulting reviews that result in a written review document(s), differ for paper or electronic submissions:

A. Paper submissions

1. On the “Review Request and Movement Form” check the first box beneath the comment field to confirm that you sent the electronic files. Ensure that the form is complete (for example, it has the name and division code of the requestor as the recipient).
2. Attach the review documents to the inside cover of the first jacket in the submission.
3. Return all materials provided with the request for the consult to the requesting division through the DCU.
4. Forward the electronic file(s) related to your review for archiving.

³ Each electronic file will have a unique name reflecting the specific submission code and number (i.e., P0123a1s.rev).

⁴ “Clean” refers to a document stripped of revision marks, hidden text, and other codes not appropriate for the final document. See P&P 1243.3005 on how to create clean electronic files.

⁵ To get the comment window in ONFI, you should select “Complete Review” on the Reviewer Notification form and then select the appropriate description in the “Complete Consulting Review” window. This will then bring up the comments window. For more information on completing ONFI submissions, refer to the ONFI manual.

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- a. Create an email addressed to the “CVM ONADE Records” mailbox. Make the subject of this email the document type code, the document number, the submission type code, the submission number, the subclass code, and the package ID of the consulting review as it is written in STARS (e.g., “I-012345-P-0123-EF (A1)”).⁶ For consulting reviews that involve more than one administrative file, send a separate email for each administrative file.
 - b. Attach the electronic file(s) to the email.
 - c. Complete the text of the email. The text of the email must include the reviewer assigned the consult in STARS, the name of the reviewer that requested the consult, and how many files are attached.
 - d. Send the e-mail at the time you forward the paper documents to the DCU to close out the consulting review.

B. Electronic submissions made through our Outlook Notification and File Integration (ONFI) system

1. Complete a STARS electronic submission “Consulting Review Return Form”. Staple this form to an empty manila folder.
2. Attach a hard copy of the review documents to the inside cover of the manila folder.
3. Forward the paper review documents to the requesting division through the DCU.
4. Forward the electronic file(s) for archiving. When you forward the paper documents to DCU, attach the electronic files to the reviewer notification screen for the submission in STARS and click on the “Complete Review” button to close out the consulting review.⁷ Do not send an e-mail or files to the “CVM ONADE Records” mailbox. These files are automatically archived into the Corporate Document Management System (CDMS).

⁶ If the subject line of the email is not in the correct format, the email will be returned to you for correction of the subject line.

⁷ For instructions on completing ONFI submissions, refer to the ONFI manual.

The archived paper and electronic copies are the official paper and electronic copies of the documents. In order to maintain document version control and information integrity, the agency does not support the retention or distribution of additional paper or electronic copies.

VI. AMENDED REVIEW DOCUMENTATION

Once the consulting review has received all of the necessary signatures and is in the DCU outbox, or picked-up by the DCU, the review package is considered final. As a final review the review is an administrative record and cannot be altered. If a significant change to a review is warranted that will significantly change the recommendations or conclusion of the review, immediately contact the requesting reviewer to inform them of the necessary changes and to determine if the primary review division completed the final action for the submission. Typographical and grammatical errors are not significant changes unless such an error changes the meaning of a conclusion or recommendation of the review.

A. If the final action for the primary submission (AA package) is not completed:

Contact the reviewer who requested the consulting review and ask them to send you a new request for a consulting review through STARS. Create an amended review and follow division procedures for concurrence.⁸ Follow the steps as in section V for completing the new consult request. Clearly indicate on the “Review Request and Movement Form”, or on the electronic submission “Consulting Review Return Form” for electronic submissions (ONFI), that the folder contains an amended review.

B. If the final action for the primary submission (AA package) was completed:

Contact the reviewer who requested the consulting review and determine if the changes will substantially affect the conclusions of their review or the content of the letter. If the answer is yes to either situation, ask the primary review division to request a Q submission from DCU (see P&P 1243.3030 for instructions on correcting final action packages). The division with the AA submission will send out the appropriate consulting review requests for this Q submission. The consulting reviewer will return the amended documents under the Q submission according to section V of this document.

⁸ See P&P 1243.3009 for instructions on how to create amended reviews.

VII. CORRECTING DEFICIENT CONSULTING REVIEW PACKAGES

If DCU finds that a consulting review package is incomplete, they will return the review package to the consulting division for correction. For example, a package is incomplete if a consulting reviewer did not return all volumes of the submission they received. Similarly, if the requesting division finds the returned package is incomplete, they should return the consulting review package through STARS to the consulting division for correction. The consulting review division should closely examine the returned submission and correct all deficiencies.

VIII. SUMMARY OF PROCESSING FOR COMPLETED CONSULTING REVIEWS

When the ONADE personnel in the division assigned the consulting review complete their review and receive the appropriate concurrence, the review documentation is ready for paper and electronic archiving. Place the paper copy of the consulting review package in the DCU outbox for pick-up; DCU will deliver the package to the individual who requested the consult.

For paper submissions, send an email to the “CVM ONADE Records” mailbox with an electronic copy of the review attached (see details above). The manager of the “CVM ONADE Records” mailbox moves the electronic copies of the documents to a “pre-archive” folder for the applicable administrative file(s) and sends an email to the consulting reviewer and the reviewer who requested the consult notifying them that the documents are available in the “pre-archive” area. The “pre-archive” area is on our R: drive. Documents in the “pre-archive” area can be viewed and used for copying and pasting of information into correspondence or other documents associated with the submission. Files held in the “pre-archive” area cannot be modified or deleted. The “pre-archive area” holds the files until the DCU completes the final action on the submission.⁹ Once the final action has been completed for a submission, all related electronic files are moved to the office archive.

For electronic submissions (ONFI), attach the electronic files of the review documentation to the Notification screen in STARS, select the appropriate final action, and complete the necessary concurrence. The consulting review package is returned to the requesting division through DCU and the electronic files are held in ONFI until the AA reviewer finalizes the submission.

IX. REFERENCES

CVM Program Policy and Procedures Manual

1243.3005 - Creating clean electronic documents

1243.3009 - Format and style conventions for reviews and submission summaries

1243.3030 - Completing final action packages

X. VERSION HISTORY

November 19, 2003 – The information in this document was originally contained in ONADE P&P 1243.3030 (November 19, 2003 version).

September 5, 2007 – This information was pulled from 1243.3030 and a separate P&P created. This P&P updates the process to include the closing out of consulting reviews for electronic submissions, the process for amended reviews, the single process for handling electronic files we generate when reviewing and responding to paper submissions, and a summary of the new procedures for handling electronic files.

March 6, 2008 – Minor grammatical errors corrected.

May 14, 2008 – Minor adjustments made in formatting of the document.

December 4, 2008 – Section IV revised to clarify on what color paper consulting reviews and attachments to reviews are printed or copied and identify responsibilities when preparing enclosures for letters.

⁹ See P&P 1243.3030, for a summary of procedures for archiving final action packages.