
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

CLOSING OUT CONSULTING REVIEWS FOR SUBMISSION
TRACKING AND REPORTING SYSTEM (STARS) SUBMISSIONS

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I. PURPOSE

This document describes the process 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. When this is the case, these individuals are called consulting reviewers for the submission, and the review they prepare is called a consulting review.

Where the review of a submission requires one or more consulting reviews, the primary reviewer (i.e., the reviewer of the AA package) should request these reviews through Appian within five days of receiving the submission, or as specified in the project management timelines. Prompt requests for consulting reviews will ensure that the consulting reviewer has sufficient time to perform their review(s) and prepare any necessary documentation. See P&P 1243.3200 for additional information on how to request a consulting review.

There may be more than one level of consulting reviews needed. A consulting review for a submission requested by the primary reviewer through Appian is identified using a sequential letter, starting with A, followed by the number 1. Multiple consulting review requests from the primary review division are sequentially identified using the next letter of the alphabet. The first consulting review request is the A1 package. The second consulting review requested is the B1 package and so on. Often a consulting reviewer determines they need consults on the package assigned to them. When this is the case, a consulting reviewer for a submission will request a consult of another reviewer through Appian. This secondary consult (a.k.a. a sub-consult) will be created using the same letter assigned to that consulting review package and the next sequential number. For example, when the consulting reviewer assigned the "A1" package requests a secondary consult, the created consult will be an "A2". Additional consulting reviews of the "A1" or "A2" submission would have sequential numbers (e.g., "A3", "A4", and so on).

III. RETURNING THE CONSULT SUBMISSION IN APPIAN

The consulting reviewer is responsible for reviewing the information in the submission assigned to them, preparing any necessary review documentation consistent with P&P 1243.3009 on format and content for reviews, and returning the review documentation through Appian to the requesting reviewer. When the consulting reviewer returns their consult in Appian, it will include their review documentation and any accompanying attachments, even those attachments that are intended to be sent to the sponsor.

When returning consulting review packages in Appian, the consult and any amendments must be returned separately.

When creating consults to linked submissions, only one consult to the lead submission should be generated. The lead submission consult will need to be returned including a list of all the linked submissions at the top of any review documentation. A copy of the consult review documentation will be automatically placed in CDMS for each of the linked submissions when the lead parent submission is closed.

IV. RESPONSIBILITIES FOR CLOSING OUT THE CONSULTING REVIEWS

After completing their review, consulting reviewers will assemble all the review documentation. If a consulting reviewer requested an additional consulting review, the secondary consult must be returned before closing their review. For example, if the "A1" consultant requested an additional (i.e., "A2") consult, the "A2" consult must be returned to the "A1" consultant before the "A1" consult can be returned to the primary reviewer.

Some consulting review requests will not result in a written consulting review document. In these cases, the consulting reviewer will write a comment in the Comments box during the Consult Return Process in Appian. Appian will generate a comment document from the Comments box and this will be attached to the consulting review package that is returned to the reviewer who requested the consult.

A. ONADE submissions with ONADE consults

The consulting reviewer will return their consult using the Appian CVM ONADE Final Actions workflow, which is located under the Records tab. All review documentation and supporting information should be uploaded into Appian by the consulting reviewer. The consult return package should be routed through the proper sign-off chain. As each person in the chain signs off on the consulting package, Appian will apply electronic signatures to the appropriate documents as designated by the consulting reviewer. The Appian consult return process closes the consult in STARS and an email is sent to the reviewer who requested the consult notifying them the consult has been returned. The email includes a hyperlink to the consulting review package. This email will be sent from "notify-consult-requestors". An email is also sent to the consulting reviewer to indicate that the consulting review package has been successfully returned. The review documentation for the consulting review package remains in Appian until the primary reviewer closes out their submission (i.e., the AA package). Once the AA

package is closed in Appian, all review documentation for the consulting reviews, as well as the AA package, review is moved to CDMS.

B. ONADE submissions with outside ONADE consults

For ONADE submissions that require a consult outside of ONADE (e.g., a consult to the Office of Surveillance and Compliance (OSC)) the primary reviewer creates the consult within Appian similar to creating a consult for someone within ONADE. An email is sent to the appropriate division automatically from Appian notifying them that a consult exists. When the consulting reviewer completes their review, the consulting review package is returned to the primary reviewer or consult requestor using the Appian consult return process as outlined in Section A above.

C. Outside ONADE submissions with ONADE consults

For submissions that originate outside ONADE (i.e., the AA package is NOT an ONADE submission) the consult requester creates the consult within Appian similar to creating a consult within ONADE. An email is sent to the appropriate division automatically from Appian notifying them that a consult exists. If the primary reviewer is from the Office of Minor Use and Minor Species or the Division of Animal Feeds in OSC, then the ONADE consulting reviewer will return their consult using their Final Action workflow. In all other instances, the ONADE consulting reviewer will use the CVM ONADE Final Action workflow to return the consult. The consult requester (i.e., non-ONADE reviewers) will receive an email notifying them that the consult has been returned and the email will contain a hyperlink to the consulting review package.

V. AMENDED REVIEW DOCUMENTATION

Once the consulting review has been returned using Appian, the consulting review package is considered final and cannot be altered. If the consultant identifies significant changes that impact the recommendations or conclusions of the original review after the consult has been returned, they should notify the consult requester that an amended review is needed. 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 and a consulting review needs to be amended:

The consulting reviewer will contact the consult requester and ask for another consult request through Appian. The consulting reviewer will create an amended review and follow division procedures for concurrence.¹

The completed consult documents reside only in Appian until the AA package is closed. Once the AA package is closed all review documents, including all consulting review documents are moved to CDMS.

¹ See P&P 1243.3009 for instructions on how to create amended reviews.

B. If the final action for the primary submission (AA package) was completed and a consulting review needs to be amended:

The consulting reviewer should contact the consult requester to determine if the changes will substantially affect the conclusions of their review or the content of the letter issued. If the answer is yes to either situation, contact the primary reviewer of the submission (i.e., the AA package) so they can create a Q submission in Appian (see P&P 1243.3250 for information on creating a Q submission and P&P 1243.3030 for instructions on correcting final action packages). The primary reviewer will send out the appropriate consulting review requests for this Q submission. The consulting reviewer will return their consult with the amended documents under the Q submission according to section V of this document.

VI. REFERENCES

CVM Program Policy and Procedures Manual

1243.3009 - Format and style conventions for reviews and submission summaries

1243.3030 - Completing final action packages

1243.3250 – “Q” Submissions: Agency Initiated Actions

VII. 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.

June 18, 2010: Updated the document to reference the ERA process. Clarified the instructions for electronic submission.

October 9, 2012: Updated to correct for new Appian electronic return process.

July 2, 2013: Updated to reflect the use of Appian by CVM Offices outside ONADE.

April 8, 2014: Minor editorial changes to reflect that consults are now created using an Appian process

July 8, 2016: Minor formatting revisions.

June 24, 2019: Minor word changes. Updated to remove ERA P&P references, and removal of reference to P&P 1243.3005 Creating Clean Electronic Files. Also, updated to include information about creating the Q submission in Appian.