
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 consulting review documentation and 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 and for information on how the different levels of consulting review are identified.

III. CONSULTING REVIEW DOCUMENTATION

Consulting reviewers will review the information in the submission assigned to them and determine whether to prepare a consulting review or if they can effectively convey the information, they want the primary reviewer to have, their feedback, or assessment via other acceptable means (e.g., commenting on a shared document like a memorandum of conference,¹ using the Appian comment box). Preparation of a consulting review using the office review template is appropriate when the information being conveyed can generally be described as complex or in-depth scientific or policy discussions, detailing science, or policy issues, capturing scientific/regulatory decision-making, information that

¹ See 1243.3025

has required formatting (e.g., Freedom of Information Summary language) and documentation that is longer than a few sentences.²

Alternatively, consulting reviewers may utilize the Appian comment boxes to provide brief feedback or to note comments were provided on a shared document. Use of the Appian comment box by the consulting reviewer instead of preparing a consulting review is appropriate when the information being conveyed can generally be described as straight-forward, not complex and can be captured in a few sentences, though some examples listed below may be up to a few paragraphs (e.g., memorandum of conference comments).

Examples of when the use of the Appian comment box may be appropriate include but are not limited to:

- Administrative comments (e.g., approval package prepared, see review documentation in another file)
- Comments for the memorandum of conference
- Comments indicating that language was provided on a shared draft of meeting documentation (MOC and letter)
- Returning a consulting review request with no review required, with or without a brief explanation
- Statement or explanation that a product does not need a microbial food safety review
- Brief explanation for why a categorical exclusion previously granted is still acceptable
- Closing out amendments consulting reviewers frequently reference the lead submission in the comment box with a statement that says something like 'Comments provided under X-#####-X-####-XX, dated Month dd, YYYY,'
- Statement that the sponsor made request change(s) and there are no further comments

The office supports judicious use of the Appian comment fields because it can increase efficiency as long as we maintain the proper balance between time savings and effective communication and proper documentation of our scientific and regulatory decision making. Information in the Appian comment boxes is preserved in the administrative file.³

If you have a question as to whether you should prepare a consulting review or provide your input using the Appian comment field, discuss this with the other impacted reviewer(s) and your team leader.

IV. RETURNING THE CONSULTING 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

² See P&P 1243.3009 on writing a review and P&Ps 1243.5761 and 1243.5762 on preparing FOI Summaries.

³ When an Appian comment is included in our records, the naming convention applied is similar to other documents. It will appear as 'comment_X-#####-X-####-XX.pdf'.

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.

V. RESPONSIBILITIES FOR CLOSING OUT THE CONSULTING REVIEW

After completing their review, consulting reviewers will assemble all the review documentation, if applicable. If a consulting reviewer requested an additional consulting review (a.k.a. secondary or sub-consult), the secondary consult must be returned before closing their review. For example, if the A1 consultant requested an additional consult (i.e., the A2 consult), the A2 consult must be returned to the A1 consultant before the A1 consult can be returned to the primary reviewer.⁴

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 Submission 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 ONADE 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.

⁴ See P&P 1243.3200 for information on how the different levels of consulting review are identified.

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 requestor 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 Appian (CVM OMUMS Final Actions or CVM OSC EDSR eReviews). In all other instances, the ONADE consulting reviewer will use the CVM ONADE Final Action workflow to return the consult. The consult requestor (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.

VI. 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 requestor 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 on Primary Submission (AA Package) Is Not Completed and a Consulting Review Needs to be Amended:

The consulting reviewer will contact the consult requestor and ask for another consult request through Appian. The consulting reviewer will create an amended review and follow division procedures for concurrence.⁵

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.

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 requestor 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

⁵ See P&P 1243.3009 for instructions on how to create amended reviews.

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.A. of this document.

VII. REFERENCES

CVM Program Policies and Procedures Manual – ONADE Reviewer’s Chapter

1243.3009 – Format and Style Conventions for Reviews and Submission Summaries

1243.3025 – Preparing Meeting Documentation (i.e., Early Response Letter, Memorandum of Conference, Acknowledgement Letter, Other Review Documentation)

1243.3030 – Completing Final Action Packages for Submission Tracking and Reporting System (STARS) Submissions

1243.3200 – Routing a Request to Obtain a Consulting Review of a Submission Tracking and Reporting System (STARS) Submission

1243.3250 – Q Submissions: Agency-Initiated Actions

1243.5761 – Freedom of Information (FOI) Summary for Original and Supplemental New Animal Drug Applications (NADA)

1243.5762 – Freedom of Information (FOI) Summary for an Animal Drug Availability Act (ADAA) Medicated Feed Combination New Animal Drug Application

VIII. 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.

April 21, 2021 – Updated to remove information from section II on how the different levels of consulting review are identified to the P&P on requesting consulting reviews 1243.3200 and update titles for some of the references.

July 1, 2021 – Updated to include information that was previously an ONADE policy on use of Appian comment fields in lieu of preparing a consulting review. The information that was in that policy is now contained in the new section III of this document called Review Documentation. New references to existing P&Ps were also added to the footnotes and reference section of the document.

November 8, 2023 – Cyclical quality management review conducted, and no substantive updates were necessary. The document was put into the current template format and the font updated from Verdana 10-point to Arial 11-point font to align with the FDA Visual Identity Program approved font. Updated the Reference section to reflect the title change of P&P 1243.3025.

March 22, 2024 – Updated to fix a typo on Heading II for the word consulting. Did a check for other grammar issues and extra spaces.