
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

COMPLETING FINAL ACTION PACKAGES FOR SUBMISSION TRACKING AND REPORTING SYSTEM (STARS) SUBMISSIONS

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I. PURPOSE

This Policy and Procedure document (P&P):

1. Applies to all Office of New Animal Drug Evaluation (ONADE) personnel completing final action packages for all Submission Tracking and Reporting System (STARS) submissions except approval packages for which there is a separate P&P,¹
2. Provides a list of steps to follow when preparing the final action package for a submission, ensuring completeness of the administrative file,²
3. Describes the process for closing out the final action package in the Appian Application Portal³ (Appian), and
4. Describes how to add documents not associated with a pending STARS submission to the administrative file.

II. ENSURING THE ACCURACY OF THE FINAL ACTION PACKAGE

A final action package contains all review documentation generated by ONADE (i.e., review, consulting review, letter to the sponsor or outside party, etc.) in response to a submission made to ONADE or agency-initiated (Q) submissions.

Before ONADE personnel upload a final action package into Appian, the person completing the final action package needs to:

¹ For detailed information on final actions on approval packages, you should refer to P&P 1243.3800, Preparing and Processing an Approval Package.

² See P&P 1243.2010 for Responsibilities for Creating and Keeping records.

³ See the CVM ONADE Appian User Guide on the ONADE Electronic Documents Submission and Review (EDSR) project SharePoint site.

Internal information redacted

1. Confirm the accuracy of the information in the final action package,
2. Make sure that all appropriate documents have been prepared and are complete,⁴ and
3. Ensure that your division management reviews completed documents per your division's internal quality control (QC) procedures.

III. PREPARING FOR FINAL ACTION

A. Consulting reviews

The primary reviewer is responsible for ensuring all consulting reviews and corresponding amendments have been returned through Appian before closing out a submission. Appian sends an email to the consult requestor at the time the consulting review package is returned.

There are cases when divisions are not consulted through Appian but their input is requested (e.g., CVM Policy Staff (HFV-6), OSC Adverse Reactions, ONADE Policy Team). For example, we typically email questions to the ONADE Policy Team. If you have a situation where a formal consult was not requested, discuss with your team leader how to incorporate the supplied information into the administrative record.

B. Review summary

The primary reviewer should complete the review summary for all submissions where required. For notice of claimed investigational exception (NCIE), minor changes and stability reports (MCSRs), and chemistry, manufacturing, and controls (CMC) supplements, the review summary is optional and is filled in at the discretion of the reviewer.

The review summary can be completed in two different ways:

1. Place the review summary text in the "Review Summary" field comment box during the closing out process in Appian.
2. Use the "Review Summary" button in STARS. If the review summary is added in STARS prior to closing out in Appian, the reviewer's comments will pre-populate into the corresponding section of Appian.

The review summary should be brief (up to 500 characters), reflect the nature of the submission, decisions made, and any other information of particular importance. If the purpose of submission is unclear for any submission type, the review summary should be used to clarify the purpose. While the contents of this field do not replace reading ONADE work products, it should be sufficient to answer basic administrative and historical questions. If the drug product's proprietary name is provided in the review summary, it should be formatted the same as in the review documentation for continuity. Use the drug product's

⁴ Follow the procedures described in P&P 1243.3005 to prepare clean electronic documents.

established name if the product does not have an approved proprietary name or uses the drug product's established name as its product name.

C. Amended submissions

If a submission under review has been amended, the amendment will automatically close out in Appian once the original submission is closed out. The primary reviewer will initiate final action on the original submission only.

D. Linked submissions

There are rare instances when certain submission types (e.g., G, Z, Y) will be linked to another submission in eSubmitter. A linked submission is created by a sponsor using eSubmitter and it lets ONADE know that one submission is referencing another, and it may involve one or more administrative files. In these cases, the lead submission (marked by an "L" in STARS) will be the submission on which to initiate final action and will be the only submission from the pair that will be on the primary reviewer's dashboard in Appian. The non-lead submission(s) will be marked in STARS with an asterisk identifying it as the linked submission. Only the lead submission requires a final action code and processing through Appian. All linked submissions will automatically close with the lead submission and receive the same final action code.

IV. THE FINAL ACTION PROCESS

ONADE personnel completing a final action package will close it out through the Appian portal. This is for all submissions that result in ONADE-generated documents or reviewer comments, whether we received the submission in paper, which is scanned into STARS, or as an eSubmitter submission. All review and final action package processes occur electronically, and the Appian steps are the same.

Refer to the CVM Appian User Guide for examples of and additional details for each step. To start the process, the reviewer should:

1. Open the Appian portal and choose the appropriate submission from the dashboard.
2. Click on the submission, confirm it is correct and ready to initiate final action, and start the Appian close out process.
3. Verify that Appian has imported all associated consulting reviews. If a consulting review remains outstanding, the primary reviewer should cancel the Appian process and contact the consulting reviewer.
4. Use the "Continue" button to move through each step of the process. The primary reviewer is the "Initiator" in Appian. If the initiator encounters a problem, there are opportunities during each step to stop, go back, or cancel the final action until initiator sign-off.
5. Ensure the Final Action code is correct.

6. Be aware of the Office's and individual division management's clearance process for each type of final action and choose the appropriate clearance chain for each. If a team leader or management signature is not necessary for a particular package, select "Initiator Only".
7. Sign-off on the package once all documents have been uploaded.

After the initiator (primary reviewer) signs off, the package moves to the next person in the clearance chain. If an error is discovered, any of the signing authorities can reject the final action and corrections can be made. Once the error(s) is corrected, the primary reviewer (initiator) would restart the final action process. Anyone in the clearance chain can also correct the "Review Summary" field at any time until the final signature has been confirmed.

After the last person in the clearance chain signs off on the package, the primary reviewer will receive an email from Appian that the package is closed out. The submission will then automatically move from the reviewer's STARS queue to the Corporate Document Management System (CDMS) for archiving. If the primary reviewer does not receive this email and the submission remains listed in the reviewer's STARS queue after all signatures have been finalized, the reviewer will need to send an email to the Electronic Documents Submission and Review (EDSR) support mailbox to have this corrected.⁵

V. SELECTING THE APPROPRIATE FINAL ACTION CODE

There are two types of final action packages:

A. Submissions filed with no letter sent to the sponsor. This applies in two cases.

1. File No Reply

This first case is when ONADE personnel completing the final action package determine that the submission should be placed into the administrative file with no formal response to the sponsor, and there is no documentation prepared; therefore, there is nothing to upload into Appian. The primary reviewer will provide submission comments in a pre-designated field in Appian when prompted. The final action code for this type of package is "Submission filed with no review documentation; no letter sent" (FNR).

2. File No Reply with Memorandum

The second case is when a final action package requires review documentation, but there is no letter sent to the sponsor. This applies when the submission is filed without a reply to the sponsor but a review document (e.g., submission summary, review, memorandum to the file) is needed to document the events, discussion, or decision to ensure the completeness of

⁵ EDSR Support: Internal information redacted

FDA's record on the matter. The final action package should include the review documentation prepared. The final action code in this case is "Submission filed with review documentation; no letter sent" (FNR with memo).

For a final action that includes multiple administrative files in a single memorandum, upload the review documentation in Appian for each administrative file (e.g., separate copies of the review document for each (J)INAD included in the final action). The exception is linked submissions, which are explained in the previous section.

B. Submissions filed with a letter or other documentation sent to the sponsor.

There are many types of submissions that require either a letter or a letter plus other documentation to be sent to the sponsor. Appian provides a drop-down list of potential final action codes for each submission type.

As an additional resource, there is a list of permissible final action codes in STARS. To find the codes, go to the Corporate Database Portal (CDP), in CDP-STARS open the Quality Control menu, go to the Printed Reports Option and then select Permissible Final Actions. Select the submission type from the document type drop down list and click "submit query" to display the list of final actions. However, not all final action codes on this list are used for ONADE submissions. The primary reviewer should discuss with their team leader which final action code is appropriate for a particular final action package, if unsure.

If the final action package requires documentation to be sent to the sponsor, the reviewer will check "Yes, send to firm" for each document being uploaded that goes to the sponsor. It is the primary reviewer's responsibility to ensure that the correct documents are being sent to the sponsor. Documents such as reviews and Memoranda Recommending Approval (MRA) are internal documents only and the "No, for CVM records only" box should be checked.

Certain final action packages require a signed copy of the letter to the sponsor be sent to another entity outside of FDA. One example is a food-use authorization letter where a copy is sent to the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS).⁶ In these cases, the Document Control Unit (DCU) will issue a copy of the letter and any other corresponding documents to the outside entity.

VI. ADDING DOCUMENTS NOT ASSOCIATED WITH A SUBMISSION TO THE ADMINISTRATIVE FILE

Occasionally there is a need to place documents, such as a memorandum or letter to sponsor, in the administrative file when there is no associated submission. The

⁶ P&P 1243.4040 and 1243.4041 describe the food-use authorization process.

primary reviewer will create a Q submission⁷, prepare the final action package, upload the document, and close out the package through Appian.

VII. AMENDING REVIEW DOCUMENTS

There may be cases when a substantial error is found either before or after the package has been closed out in Appian. Depending on the error, an amendment to the review documentation may be needed. This can be to amend the review from either the consulting reviewer or the primary reviewer. A substantial error is one that will significantly change the recommendations or conclusion of the document(s). Typographical and grammatical errors are not considered substantial changes unless a grammatical error changes the meaning of a conclusion or recommendation in a document.

A. Amending a consulting review

If after receiving a consulting review package, but before completing the final action package, the primary reviewer believes that a significant change to a consulting review is necessary, the primary reviewer will immediately contact the consulting reviewer to discuss the issue. If an agreement is reached with the consulting reviewer that the change can be documented in the primary (AA) review, the primary reviewer will document the discussion and agreement of the consulting reviewer. The primary reviewer may also include emailed documentation of concurrence. If the primary reviewer determines that a significant change to the consulting review and a subsequent amended consulting review is necessary, the primary reviewer will request a new consult through Appian for the appropriate consulting reviewer. The consulting reviewer will create and return an amended review^{8,9} Include the original and all amended reviews in the final action package.

B. Amending an AA review

If a significant change to one or more documents in the final action package is needed after close out of the submission, create a Q submission to provide a place for the amended reviews or revised correspondence. Where a revised letter is needed, contact the sponsor to inform them that there was an error in the previous letter and that a corrected letter will be issued. The updated review that amends the previous review's conclusions (and revised letter) should document those changes and the supporting rationale for such changes.

VIII. CORRECTING FINAL ACTION CODES

A. Final action code correction with no change to review documentation

The primary reviewer should notify their team leader and generate an Employee Resource and Information Center (ERIC) ticket if it is discovered that the final

⁷ Refer to P&P 1243.3250, Q Submission Agency Initiated Action and discuss this with your team leader if you have questions about creating a "Q."

⁸ See P&P 1243.3029 Closing Out a Consulting review for STARS Submissions.

⁹ See P&P 1243.3009 for instructions on how to create amended reviews.

action code needs to be modified after a submission has been closed. ERIC will make the correction. In your ERIC request provide the submission ID, the current final action code, and the final action code that should be used.

B. Final action code correction and review documentation change(s) is required

In this scenario, the wrong final action has been selected and the review documentation in the final action package is not correct (e.g., the submission is put through as an incomplete and it is determined after the fact that it should have been complete). The primary reviewer should notify their team leader and generate an ERIC ticket. The ERIC ticket should request the submission be returned to pending status in STARS. The reviewer must notify the EDSR mailbox to request original documentation for the submission be removed from Appian and CDMS.¹⁰ The Business Informatics Team will manually re-ingest the submission into Appian so that the submission can be closed out again with the proper review documentation. If the review documentation includes a letter to the sponsor, the primary reviewer should also contact the sponsor of the submission to inform them when the correspondence is incorrect.

IX. REFERENCES

CVM Program Policy and Procedures Manual

1243.2010 – Responsibilities for Creating and Keeping records

1243.3005 – Creating Clean Electronic Files

1243.3009 – Format and Style Conventions for Reviews and Submission Summaries

1243.3029 – Closing Out a Consulting Review for STARS Submissions

1243.3250 – Q Submission Agency Initiated Action

1243.3800 – Preparing and Processing an Approval Package

1243.4040 – Investigational Food-Use authorizations: The Role of the Primary (AA) Review Division

1243.4041 – Investigational Food-Use Authorizations: The Role of Division of Human Food Safety Reviewer

X. VERSION HISTORY

November 19, 2003 – Original version.

September 6, 2007 - The content of the original P&P 1243.3030 was updated, expanded, and separated into several P&Ps (1243.3005, 1243.3009, 1243.3029, and

¹⁰ EDSR Support: Internal information redacted
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1243.3030). The current version of this P&P updates and retains only that information directly related to closing out final action packages.

March 12, 2008 – Minor information on handling overlapping comments between reviews was included along with specific information about not changing consulting reviewer’s comments.

December 4, 2008 – Section VI. A. 3. a. revised to clarify what color paper enclosures are to be printed on and how many copies are prepared for the final action package.

April 3, 2009 – Multiple sections revised to add instructions and references related to the ERA process. Information with regard to the food-use authorization letter was updated and references to the food-use authorization P&Ps added. References to the ONADE Reviewer Reference Page were changed to inside.FDA (FDA intranet) were added.

May 17, 2017 – Multiple sections revised to delete outdated process information and add instructions related to processing final action packages using the Appian Application Portal.

August 7, 2018 – Revised Section V. 1. B. File No Reply with Memorandum to include examples of the type of review documentation that might be filed in this situation. Updated the term established name to drug product established name wherever it appeared.

December 17, 2018 – Revised Section III. B. Review Summary to reflect that the review summary field is not required for NCIEs, MCSRs, and CMC supplements. This decision went through JOLT and based on a recommendation from QSB, made the decision to change the requirement that all submissions include content in the review summary field.