
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

COMPLETING FINAL ACTION PACKAGES FOR STARS SUBMISSIONS

I. Purpose	1
II. Ensuring the accuracy of STARS	2
III. Returning the submission(s) to the DCU to be finalized out	2
IV. Completing the final action form	3
V. Preparing the final action package for final actions that do not result in a letter	4
VI. Preparing the final action package for final actions that result in a letter	6
VII. Adding documents not associated with a submission to the administrative file ...	12
VIII. Amended review documents	12
IX. Correcting deficient final action packages	13
X. Summary of processing for final action packages.....	14
XI. References	15
XII. Version history	16

I. PURPOSE

This document:

- Applies to all Office of New Animal Drug Evaluation (ONADE) personnel completing final action packages for all STARS submissions except approval packages,¹
- Provides a list of the steps to follow when you prepare the final action package for a submission to assure the completeness of the administrative file,²
- Describes the information to submit to the Document Control Unit (DCU) as part of a final action package, and
- Describes how to add documents not associated with a pending STARS submission to the administrative file.

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

² See P&P 1243.2010 for ONADE's procedures for creating and keeping administrative records.

II. ENSURING THE ACCURACY OF STARS

Before a final action package leaves the review division, ONADE personnel completing the final action package are responsible for:

1. Confirming the accuracy of the information on the STARS DCU Routing Slip (Review Request and Movement Form) forwarded with the submission(s). If you have any comments or specific instructions for the DCU, write them in the “Comments/Instructions to DCU” box of the final action form.³
2. Checking that all consulting review packages have been returned and routed through the DCU before routing the final action package for clearance and processing.
3. The person assigned the submission is strongly encouraged to complete the “Summary Review” field for all submissions with reviews. This field can be accessed by using the “Review Input” button in the “Review Summary” screen of the “Reviewer’s Pending List” in STARS. To the extent possible, the brief summary (up to 500 characters) should reflect the nature of the submission, any decisions made, and any other information of particular importance. While the contents of this field cannot replace a reading of ONADE work products, it should be sufficient to answer basic administrative and historical questions.

III. RETURNING THE SUBMISSION(S) TO THE DCU TO BE FINALED OUT

ONADE personnel completing final action packages are responsible for returning all materials provided by the sponsor as part of the submission, including desk copies, and all other copies of the submission, to the DCU.^{4,5} Make certain all consulting review

³ If there are errors on the DCU Routing slip, you may request a change on the final action form but it may delay the actual finaling out of the submission. Ideally, you should identify any errors on the routing slip and request changes using the STARS correction form when you receive the submission.

⁴ In STARS, these materials are referred to as the AA package. The AA package includes the original, duplicate, triplicate, and any additional copies of the submission(s) provided by the sponsor, any supplied electronic media (CD’s, diskettes, videos), and any other artifacts (e.g., drug containers, feed bags) submitted to CVM. Where actual drug products are among the artifacts, please contact the DCU for instructions regarding their placement in the administrative file or alternate disposition.

⁵ 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.

packages have been returned. Return these materials when you final out the submission as part of the final action package.

If you have a continuing need to reference a submission on which a final action is being completed, request the return of these materials by using the STARS document request form available on the ONADE STARS page on Inside.FDA.^{6,7}

IV. COMPLETING THE FINAL ACTION FORM

ONADE personnel completing final action packages should complete the final action form appropriate to the submission(s),⁸ and be sure to:

1. Fill in the document code, document number, submission code, submission number, and submission sub-class code of each submission including all amendments in the final action package on the form,
2. Check the correct action code,⁹
3. Note any special requests in the “Comments/Instructions to DCU” box,¹⁰ and
4. Complete the routing of the final action package (see below for the routing of different final actions).
5. In addition, except for electronically submitted protocols, electronic submissions (Outlook Notification Form Integration or ONFI) require completion of the reviewer notification screen for the submission in STARS. Select the

⁶ You can also use a STARS document request form to check out drug containers or other artifacts that may serve an educational purpose. However, the individual making the request has the responsibility to account for and ultimately return the artifacts to the administrative file.

⁷ See the STARS page on Inside.FDA for copies of the STARS forms.

⁸ Note that for electronic submissions with ONADE review documentation, you will use the electronic submission final action form.

⁹ See P&P 1243.3033.

¹⁰ Examples include requests to make changes in STARS data fields, requests for library loan transfers, or requests to transfer files to a district office.

appropriate final action code and the appropriate concurring official in the drop down menus.¹¹

V. PREPARING THE FINAL ACTION PACKAGE FOR FINAL ACTIONS THAT DO NOT RESULT IN A LETTER

ONADE personnel completing the final action package need to submit a paper final action package for all submissions that result in ONADE-generated documents regardless of whether we received the submission as a paper or electronic submission. Electronic submissions (except for electronically submitted protocols) also require the completion of the reviewer notification screen in STARS.¹¹

There should be no pencil or ink corrections in any ONADE review documentation. Note: Prepare all review documentation (e.g., reviews, submission summaries, memos to file) on yellow paper.

A. Submission filed with no review documentation; no letter sent (FNR).

When ONADE personnel completing the final action package determine that the DCU should place a submission into the administrative file with no action, the correct final action is “Submission filed with NO review documentation; no letter sent (FNR).” Route the final action directly to the DCU.

1. Paper submission

- a. Write “FNR,” the date of the decision, and your signature in the upper right quadrant of the first page of the original submission.
- b. Staple the completed final action form to the outside front face of the manila folder or volume containing the original submission. Select the final action code “Submission filed with no review documentation; no letter sent (FNR).”

¹¹ See the Outlook Notification Form Integration (ONFI) manual available on the CVM Intranet for further instructions on handling electronic submissions (<http://intranet.fda.gov/cvm/IT/CDP/CDP.htm>). ONFI is not used for electronically submitted protocols or for amendments to these protocols.

2. Electronic submissions (ONFI)

- a. Select “File No Reply (FNR)” in the “Final Action” drop-down menu on the reviewer notification screen for the submission in STARS.¹² In these electronic submissions, all review and final action processes occur electronically.

If your division or staff procedures require concurrence on the final action package, route the package to your team and division to obtain concurrence.

B. Submission filed with review documentation; no letter sent (FNR with memo).

Where the submission is filed without a reply to the sponsor but a review document (for example a memorandum to the file) is needed to document the decision, the correct final action is “Submission filed with review documentation; no letter sent”. The final action package should include the review document, printed on yellow paper, and the completed final action form.¹³ Document the rationale for the decision not to issue a letter in the review document, not on the submission itself. Route the final action directly to the DCU.

1. Paper submissions

- a. Staple the completed final action form to the outside front face of a separate manila folder and attach the review document to the left inside face of that folder. Select the final action code “Submission filed with review documentation; no letter sent (FNR w/ memo).” For a final action that includes multiple administrative files in a single “memo”, you should provide a yellow copy of the review documentation for each administrative file (for example, separate copies of the review document for each INAD included in the final action).
- b. Prepare and send the electronic files for archiving as described in Section VI. B. below.

¹² See the Outlook Notification Form Integration (ONFI) manual for further instructions on handling electronic submissions.

¹³ The use of yellow paper facilitates the easy identification of CVM-created records in the administrative file for later reference.

-
2. Electronic submissions (ONFI)
 - a. Select “File No Reply with Memo (FNR w/memo)” in the “Final Action” drop-down menu on the reviewer notification screen for the submission in STARS.¹⁴
 - b. Attach the electronic copy of the review document. All electronic files should be “clean” and identical to the printed version.¹⁵ Do not send an e-mail or files to the “CVM ONADE Records” Outlook mailbox for electronic submissions, these files are automatically archived into CDMS.
 - c. For the paper final action package, staple the completed final action form to the outside front face of a manila folder and attach the review documentation to the left inside face of the folder. Do not print out the electronic submission; however, the review (memo to file) should state that CVM received the submission electronically.

If your division or staff procedures require concurrence on the final action package, route the package to your team and division to obtain concurrence.

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. PREPARING THE FINAL ACTION PACKAGE FOR FINAL ACTIONS THAT RESULT IN A LETTER

ONADE personnel completing the final action package need to submit a paper final action package for all submissions that result in a letter regardless of whether we received the submission as a paper or electronic submission (through ONFI). All submissions that result in a letter will have either a submission summary or a review associated with them. For electronic submissions, do not print out the submission; however, the review should state that CVM received the submission electronically.

¹⁴ See the Outlook Notification Format Integration (ONFI) manual for further instructions on handling electronic submissions.

¹⁵ “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.

Electronic submissions also require the completion of the reviewer notification screen in STARS.¹⁶

A. Preparing the paper copy of the final action package

In addition to the submission, the final action package contains the following:

1. The final action form

Staple the completed final action form to the outside front face of a manila folder. Route the final action package to your team, division, and then DCU by entering the correct HFV codes.

2. The letter and enclosures issued to the sponsor

Place the issuing letter to the sponsor, all enclosures, and an addressed envelope, under a transparent protector sheet.¹⁷

3. Distribution and official file copies of the letter and enclosures

- a. Any submission for which the final action package includes a letter, prepare only one copy of the letter and enclosure for the administrative file. This official file copy of the letter and any accompanying enclosures are on pink paper. The pink copy of the letter will contain all the administrative information, including concurrences. Note that if a consulting reviewer has prepared an enclosure to accompany the letter, you will need to make the necessary white and pink copies. Make a white photocopy to enclose with the letter and a pink photocopy to put in the administrative file. The administrative file should always contain copies of all enclosures to complete the administrative record. For a letter that responds to multiple submissions, provide a pink copy of the letter with all enclosures for the administrative file of each submission (for example a letter addressing submissions from multiple INADs or NADAs should have a pink copy for each administrative file).

¹⁶ See the Outlook Notification Format Integration (ONFI) manual available on the CVM Intranet for further instructions on handling electronic submissions (<http://intranet.fda.gov/cvm/IT/CDP/CDP.htm>).

¹⁷ Prepare the letter to the sponsor, all copies of the letter, enclosures, and the envelope consistent with P&P 1243.3010, 1243.4070 (INAD E with ERA), or 1243.4075 (INAD P with ERA), as applicable.

b. When necessary, identify to whom additional copies of the letter are to be distributed in the cc: block.¹⁸ Include enough copies, on white paper, of the official file copy of the letter and enclosures for distribution. Also include the necessary addressed envelopes.

i. Paper copies distributed within the FDA¹⁹

Write the intended recipient's name and mail code in pencil in the upper right-hand corner on the first page of each copy. The DCU will distribute these copies as part of processing the final action package. If the DCU needs to mail the copy, such as to an FDA district office, provide an addressed envelope in the final action package.

ii. Paper copies sent outside the FDA

Certain final action packages require that 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 USDA/FSIS.²⁰

Include a photocopy of the unsigned letter to the sponsor with the cc: line checked or circled and flag it for the person who will sign all copies of the letter. The DCU will date-stamp the photocopy of the letter. Include an envelope addressed to the entity in the final action package. As a courtesy and to inform the sponsor, the letter to the sponsor should indicate in the cc: block that a copy has been issued to the entity outside of FDA.

As a general rule, it is important to include enclosures with copies of letters sent to parties outside of FDA, such as the EPA. This is to ensure the letter recipient has all relevant information.

¹⁸ The DCU is responsible for the mailing of materials such as administrative records to other agencies or parts of FDA (such as district offices). For materials sent to other agencies, either provide the DCU with appropriately sized addressed envelopes (or other containers) for the materials or consult with the DCU regarding an appropriate way (such as preprinted labels) to ensure the packages are appropriately addressed.

¹⁹ It is ONADE policy to limit paper copy distribution within the office to the Green Book.

²⁰ P&P 1243.4040 and 1243.4041 describe the food use authorization process.

-
4. Pink copy of division notification email related to INAD E and P submissions, as applicable²¹
 5. Reviews and other CVM-created administrative records

For a final action that addresses submissions within multiple administrative files in a single letter, provide a yellow copy of the review documentation for each administrative file (for example, separate copies of the review documents for each INAD included in the final action).

Attach the following items to the inside right face of the manila folder in the following order from front to back:

- a. The letter for the sponsor, enclosures, and addressed envelope, covered with a transparent protector sheet,
- b. The distribution copies, if applicable, of the letter and enclosures, and addressed envelopes, and
- c. The pink copy of the letter and enclosures for the administrative file.
- d. The pink copy of the protocol concurrence, protocol non-concurrence, or End Review Amendment-related (ERA) notification email.

Attach reviews and other CVM-created review documents to the inside left face of the manila folder in the following order from front to back:

- a. The submission summary (when prepared as a stand-alone document),
- b. Primary review and supporting documents, followed by the primary ERA review (if applicable),²² and
- c. Consulting reviews and supporting documents, followed by the consulting ERA reviews, as applicable. If the final action package includes more than one consulting review, place the consulting reviews (and ERA reviews, as applicable) in order of the package ID by letter then number (for example, A1, A2, B1, and B2).

²¹ Refer to P&P 1243.4070 and 1243.4075, as applicable

²² Examples of supporting documentation include copies of slides from presentations, copies of referenced scientific articles, and memos to the file.

There should be no pencil or ink corrections in any ONADE review documents.

Table 1: Placement of review documentation in manila folder for a final action package with a letter.

Left Face of Folder	Right Face of Folder
<ol style="list-style-type: none"> 1. Submission summary 2. Primary review and supporting documentation and primary ERA review if applicable. 3. Consulting reviews and supporting documentation and consulting ERA reviews if applicable. 	<ol style="list-style-type: none"> 1. Letter for sponsor with enclosures and envelope 2. Distribution copies of letter and enclosures with envelope 3. Official file copy of letter and enclosures 4. Pink copy of division notification email for INAD E and P submissions, as applicable.

B. Preparing and sending electronic files for archiving

There should be an electronic file for each ONADE review document included in the final action package. If the review documents pertain to multiple submissions within a single administrative file (i.e., INAD file, NADA file, etc.), provide an electronic file of each document for the administrative file. If the review documents pertain to multiple administrative files, provide electronic files for each administrative file.²³ All electronic files should be “clean” and identical to the printed version.²⁴ If any CVM review document(s) from outside of ONADE has not already been forwarded for archiving (for example, a consulting review from the Office of Surveillance and Compliance) instruct the author to email an electronic copy of their document(s) to the “CVM ONADE Records” mailbox.

²³ Each electronic file will have a unique name reflecting the specific submission code and number (i.e., P0123efd.rev).

²⁴ See P&P 1243.3005.

1. Paper submissions

- 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 final action package as it is written in STARS (for example, “I-012345-P-0123-EF (AA)”)²⁵. For final actions that involve more than one administrative file, send a separate email for each administrative file.
- b. Attach your electronic files to the email.
- c. Complete the text of the email. The text of the email must include the reviewer assigned the submission in STARS and how many files are attached.
- d. Send the e-mail at the time the final action package leaves the division for final clearance and processing.²⁶

2. Electronic submissions (ONFI)²⁷

Attach your files for the ONADE review documentation to the reviewer notification screen for the submission in STARS prior to clicking on “Rqst Concur” button. This moves these files forward for ultimate archiving in the Corporate Document Management System (CDMS). Do not send an e-mail or files to the “CVM ONADE Records” mailbox.

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.

²⁵ 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.

²⁶ For final action packages that are reviewed by the Quality Assurance team (QA), the QA team will send an email notifying you when to send the final electronic documents to the CVM ONADE Records mailbox in Outlook.

²⁷ An exception is made for electronically submitted protocols. Electronically submitted protocols are processed according to procedures used for paper submissions.

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

Occasionally there is a need to place a document, such as a memorandum, in the administrative file when there is no associated submission. To do this, create a Q submission.²⁸ When you prepare the final action package for the Q submission, attach the document to the left inside face of a manila folder and staple a completed final action form to the front face of the folder. Also attach an electronic version of any document you create to an email and send it to the “CVM ONADE Records” Outlook mailbox for archiving. 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 final action package as it is written in STARS (for example, “I-012345-Q-0123-OT (AA)”). The text of the email must include the name of the author of the document and how many files are attached.

VIII. AMENDED REVIEW DOCUMENTS²⁹

If a significant change to one or more documents in the final action package is warranted that will significantly change the recommendations or conclusion of the document(s), you may need to create an amended review. Typographical and grammatical errors are not significant 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, you believe that a significant change to a consulting review is necessary, immediately contact the consulting reviewer to discuss the issue. You are not to change the consulting reviewer’s comments, conclusions, or transmit to sponsor section. If you reach agreement with the consulting reviewer and determine the change can be documented in the AA review, you may document the discussion and agreement of the consulting reviewer in the AA review. You may also include email documentation of concurrence. If you determine that a significant change to the consulting review is necessary and an amended review from the consulting reviewer is necessary, send a new consult request through STARS to that consulting

²⁸ If you have questions about creating a Q submission, discuss this with your team leader or division director.

²⁹ Review documents created for ERAs are not considered “Amended Review Documents.” Refer to P&P 1243.4070 or 1243.4075 for creation of ERA-related review documents.

reviewer. The consulting reviewer will create and return an amended review.^{30,31} Do not discard any original review documentation that is subsequently amended. Include the original and all amended reviews in the final action package.

B. Amending an AA review.

Once the final action package has received all of the necessary signatures and is in the DCU outbox, or picked-up by the DCU, the documents are considered final. There should be no changes to any of the documents contained in the package. If a significant change to one or more documents in the final action package is warranted, immediately contact the DCU to determine if they completed the final action for the submission.

If the DCU has not completed the final action, request that DCU return the final action package. The appropriate personnel should create an amended document for each document requiring a significant change, follow division procedures for review and concurrence, and submit the final action package with the original and all amended document(s) and electronic files for archiving as described previously.

If the DCU has completed the final action, fill out the appropriate form to create a Q submission.³² Under this Q submission create the appropriate amended reviews or revised correspondence. If the changes affect the text of the letter sent for the initial submission, contact the sponsor to inform them that there was an error in the previous letter and that we will issue a corrected letter.

IX. CORRECTING DEFICIENT FINAL ACTION PACKAGES

Upon receipt of a final action package, DCU confirms that all applicable paper and electronic files, and other supporting materials for the final action, have been returned to DCU. If DCU does not receive one or more of these components, they will contact you or division staff for immediate resolution. The review division should closely examine the returned final action packages and correct all deficiencies before returning the final action package to DCU.

³⁰ See P&P 1243.3029 and 1243.3009.

³¹ See P&P 1243.3009 for instructions on how to create amended reviews.

³² If you have questions about creating a Q submission, discuss this with your team leader or division director.

X. SUMMARY OF PROCESSING FOR FINAL ACTION PACKAGES

When the ONADE personnel in the division assigned the AA package complete all the documents in a final action package and receive the appropriate signatures, the review documentation is ready for paper and electronic archiving. Place the paper documents in the DCU outbox for pick-up.

For paper submissions and electronically submitted protocols, send an email to the “CVM ONADE Records” mailbox with an electronic copy of the documents attached (see details above). The manager of the “CVM ONADE Records” mailbox moves the electronic documents to a “pre-archive” folder for the applicable administrative file(s) and sends an email to the reviewer notifying them when the documents are available in the “pre-archive” area.³³ Once DCU receives the final action package for the submission, they will compare the paper documents received, the electronic files in the “pre-archive” area, and the information in STARS to confirm that they received all paper and electronic files before they will close out a submission. When the DCU finalizes the submission, they date stamp all paper copies of the letter, mail the correspondence associated with the final action package, move the paper documents to the DCU archive, and send the manager of the “CVM ONADE Records” mailbox an email authorizing the archiving of all related electronic files for the submission. The “ONADE Records” mailbox manager adds the necessary correspondence dates to the files and moves the files from the “pre-archive” area to the office archive. The paper and electronic versions of the documents are now in the appropriate office archives.

For electronic submissions (ONFI) except for electronically submitted protocols, attach the electronic files of the review documentation to the Notification screen in STARS, select the appropriate final action, and complete the necessary concurrence.³⁴ When the DCU finalizes the submission, they mail the correspondence associated with the final action package, move the paper documents to the DCU archive, and the electronic files enter the CDMS database. The paper and electronic versions of the documents are now in the appropriate office archives.

³³ 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.

³⁴ See the Outlook Notification Format Integration (ONFI) for further instructions on handling electronic submissions. Electronically submitted protocols are processed using procedures for paper submissions.

XI. REFERENCES

CVM Program Policy and Procedures Manual

- 1243.2010 – Responsibilities for creating and keeping records
- 1243.3005 – Creating clean electronic documents
- 1243.3009 – Format and style conventions for reviews and submission summaries
- 1243.3010 – Format and style conventions for letters
- 1243.3029 – Closing out consulting reviews for STARS submissions
- 1243.3033 – Permissible STARS action codes for STARS submissions
- 1243.3060 – Final document routing and copy distribution for NADAs, ANADAs, INADs, JINADs, master files, and suitability petitions
- 1243.3340 – Placing stamp dates on the electronic copies of letters issued by ONADE
- 1243.3800 – Approval process and 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 the Division of Human Food Safety reviewer
- 1243.4070 – Integrating an End-Review Amendment (ERA) into the Investigational New Animal Drug (INAD) Protocol (E) Submission Review Process
- 1243.4075 – Integrating an End-Review Amendment (ERA) into the Investigational New Animal Drug Data (P) Submission Review Process
- 1243.5820 - Approval letters

XII. 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 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.