
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER’S CHAPTER

REQUESTING A QUALITY CONTROL REVIEW FROM THE QUALITY ASSURANCE TEAM FOR FINAL ACTION PACKAGES SIGNED BY THE OFFICE OR CENTER DIRECTOR

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I. PURPOSE

This document describes the procedure to request a Quality Control (QC) review for approval packages and food use authorizations from the Quality Assurance (QA) Team.

II. QC REVIEW REQUEST: INFORMATION, FORMS, AND PROCEDURE

A. QC Reviews

The QA Team performs a QC review on all approval packages and food-use authorizations intended to be signed by the Office of New Animal Drug Evaluation (ONADE) Office Director or the Center for Veterinary Medicine (CVM) Center Director. This includes all original and some supplemental approval packages (i.e., all B1 and some 180-day generic non-fee supplement approvals) and food-use authorization packages. QC reviews are conducted to confirm that all documents in the packages are consistent with all relevant ONADE templates, policies, and procedures, and that the package is administratively complete.

Reviewers should only request a QC review when their review package is considered complete and ready for final action. Exceptions may be made if some package documents are incomplete or delayed due to external factors. In these cases, the primary reviewer should contact the QA Team Leader (QA TL) to discuss the package and timing of the QC review so that applicable deadlines can be met. Reviewers should refer to relevant P&Ps (i.e., P&P 1243.4040 Investigational Food-use Authorizations: The Role of the Primary (AA) Review Division and P&P 1243. 3800 Preparing and Processing an Approval Package) for descriptions of the documents that should be included in a final action package sent to the QA Team for QC review.

B. The QC Folder Location

There is a QA Team Approval Packages Draft Folder in the WORKAREA folder on the S Drive. Each division has its own folder within the main folder. Prior to requesting a QC review, the primary reviewer (PR) will create a folder within their division’s folder for the submission they want reviewed and name it using the submission ID (i.e., X-000000-X-0000-XX). Although the folder is named for approval packages, food-use authorization documents should also be placed in this folder for QC review.

Figure 1: Screenshot of QA Team Approval Packages Draft Folder



C. The QC Review Request Form

Prior to requesting a QC review in Appian, the PR will access and fill out the QC Review Request Form in the ONADE Templates folder on SharePoint. The PR should fill out the QC Review Request Form completely and place it in the newly created submission subfolder with the submission final action package.

D. Creating the QC Review Request Consult in Appian

After the PR puts the submission final action package and the QC Review Request Form in their submission subfolder on the S drive, the PR initiates the request for a QC review by creating a consult in Appian. See the CVM ONADE Appian User Guide on the ONADE EDSR SharePoint page for a description of the process for creating a consult request. The consult should be sent to the QA Team (HFV-184).

E. The QC Review Process

The QA TL assigns the consult to a quality assurance reviewer (QAR). The QAR creates a “QA Comments” subfolder within the submission folder and creates QA Comments versions of the food-use authorization letter or each document in Folder A of an approval package. These QA Comments versions are where the QAR adds comments for revisions using the comment bubbles feature of MS Word, except for the FR document, where comments will be made using the comment bubbles feature of Adobe Acrobat®. The QAR also creates a QC Review Summary document that contains the QAR’s comments.

The QC Review Summary and associated comments in the QA Comments documents will typically identify revisions the PR should make. Acceptable deviations, noted either by the PR or QAR, will be designated as “Acceptable” in bold to indicate that the deviation from the template, P&P, or submission contents has been observed, has been sufficiently explained, and does not require additional revision. Occasionally, a recommended comment may be stated as, “We recommend”.

Recommendations are not required but are provided to improve consistency, accuracy, or compliance with office policy for documents in a final action package.

The QA TL reviews the documents and the QC Review Summary comments and determines, based on the scope of the comments, whether the QC review of the submission is complete or if the submission requires a second round of QC review (second pass). A second pass is an additional QC review after the PR has addressed the initial QC review comments. Only packages of high quality with minimal revisions will qualify for a single-pass review.

F. Returning the QC Review Summary Form

If there are very few minor revisions requested and the package needs only a single pass QC review, the QAR uploads the QC Review Summary Form and returns the consult to the PR in Appian. Final action packages for food-use authorizations typically have one, initial QC review.

1. Second Pass QC Review of Approval Packages

If there are substantial revisions requested, the QAR emails the first pass QC Review Summary to the PR and copies the PR's TL and the QA TL. The consult in Appian remains open and the QAR will request a second pass QC review (after revisions are complete).

When the PR receives the email and attached first pass QC Review Summary, he or she will review the comments and revisions requested by the QAR. The QAR's comments in the QA Comments documents should be left intact; i.e., do not delete or modify the QA comment bubbles. The PR should incorporate revisions into the appropriate document(s) in Folder A and create new, clean, final documents. To avoid confusion and maintain version control, the PR should delete older versions of the final action package documents in Folder A in the QA Team Approval Packages Draft Folder and place only the clean, most recent final version of the approval package documents there. Therefore, when the package is sent back to the QA Team for the second pass QC review only the most recent documents will be in Folder A. Only the QA Comments folder will contain previous versions of documents.

If the PR does not implement a revision, the PR adds a comment bubble to the appropriate QA Comments document explaining why the change was rejected.

When this process is complete and the approval package is ready for the second pass QC review, the PR notifies the QAR by email and copies the QA TL.

The QAR conducts the second pass QC review process per Section II. E. above and updates the QC Review Summary.

When the second pass QC review is complete, the QAR returns the consult and the updated QC Review Summary to the PR in Appian.

III. CREATING THE FINAL REVIEW PACKAGE AFTER THE QC REVIEW

When the PR receives the returned consult, they should review any changes requested by the QAR.

A. When No Revisions Are Requested

For approval packages, if there are no revisions requested, the PR should load the clean, final documents from Folder A into Appian (Folder A of the submission folder in the QA Team Approval Packages Draft Folder in the WORKAREA folder). For food-use authorizations, load clean final documents into Appian from the submission folder in the QA Team Approval Packages Draft Folder in the WORKAREA folder.

B. When Revisions Are Requested

If revisions are requested, they should be implemented into the documents in Folder A (Folder A of the submission folder in the QA Team Approval Packages Draft Folder in the WORKAREA folder) or from the submission folder for food-use authorizations. The QA Comments documents should not be altered in any way, except for the addition of a comment from the PR if a requested revision is not implemented. The PR's comment should provide the reason for not implementing the change. The documents from Folder A or the submission folder should then be uploaded into Appian.

Uploading clean, final documents from the Folder A or the submission folder in the QA Team Approval Packages Draft Folder into Appian is recommended to maintain version control of the final documents. By using this process, the QC review confirms that the documents to be uploaded into Appian are clean, final documents compliant with ONADE templates and P&Ps and consistent with the submission content. The QA TL will confirm any final revisions requested and not previously reviewed in the clean documents during the concurrence process in Appian.

IV. REFERENCES

Appian User Guide

Internal information redacted.

CVM Program Policies and Procedure (P&P) Manual -ONADE Reviewer's Chapter

1243.3800 - Reviewing, Preparing, and Routing Approval Packages for Certain Abbreviated and New Animal Drug Applications

1243.4040 – Investigational Food-Use Authorizations: The Role of the Target Animal Division Reviewer

ONADE Templates and Forms

Quality Control (QC) Review Request Form

Quality Control (QC) Review Summary Approval Package Template

Quality Control (QC) Review Summary Food Use Authorization Template

V. VERSION HISTORY

July 21, 2016 - Revised to incorporate beta test recommendations. This is the original version incorporated into ONADE P&Ps.

August 13, 2019 – Revised title of the policy and procedure document to make it more informative.

December 9, 2019 – Revised the screenshot in Figure 1 to reflect all divisions in ONADE.

June 30, 2020 – Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

October 18, 2023 – Quality system review conducted and no substantive revisions were made. The document was updated to the current template. Also, ONADE is working to align all documentation to the agency's Visual Identity program and therefore, the font was changed from Verdana 10-point to Arial 11-point font.

APPENDIX 1. FLOWCHART DEPICTING THE QC REVIEW PROCESS

Requesting Quality Control (QC) Review from ONADE Quality Assurance Team (Approval and Food Use Authorization Packages)

