
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

INTEGRATING AN END-REVIEW AMENDMENT (ERA) INTO THE NEW ANIMAL DRUG APPLICATION REVIEW PROCESS

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I. PURPOSE

This document describes the procedures for:

- Integrating an end-review amendment (ERA) into the new animal drug application (NADA) and supplemental NADA review process.

This document does not apply to administrative NADAs, manufacturing supplements or supplemental NADAs as described in 21 CFR 514.8(c)(3)(i) and (ii) (labeling supplements).

II. BACKGROUND

The Animal Drug User Fee Amendments of 2008 (ADUFA II) provides for the use of the ERA process to enhance the review of non-administrative NADAs and non-manufacturing supplemental NADAs.

The ADUFA II Goals Letter states, “The term ‘end-review amendment (ERA)’ is understood to mean an amendment to an animal drug application or supplemental animal drug application ... that is requested by CVM after it has completed its review of the submitted information and determines that the submission of additional non-substantial data or information would likely complete the application.... This term does not include minor amendments that are requested by CVM during review of applications”

There are different performance goals (i.e., ADUFA deadlines) for the review of non-administrative NADAs and supplemental NADAs, based on whether we request an ERA and whether we receive a requested ERA on time. The ADUFA performance goals are the same for non-administrative NADAs and non-manufacturing supplemental NADAs; therefore, this document will refer to them both as NADAs.

If we determine that we can approve an application based on the submitted information, the ADUFA deadline for completing the review of the application is 180 days.^{1 2}

If we determine that we cannot approve an application based on the submitted information and we do not request an ERA, the ADUFA deadline for completing the review of the application is 180 days.

If we determine that an ERA would likely allow us to complete a review of the application and reach a decision on whether we could approve the application, the ADUFA deadline for requesting the ERA electronically (i.e., via email) is 180 days.

If we request an ERA and we do not receive it by Day 210, then the ADUFA deadline for completing the review of the application (without the ERA) is 220 days.

¹ From the ADUFA II Goals Letter -- “Completing the review” means conducting a complete and comprehensive review of the available information, then issuing an action letter which either (1) approves the application or (2) sets forth in detail the specific deficiencies in the application and, where appropriate, the actions necessary to place the application in condition for approval.

² Unless otherwise stated, all timeframes reference the date that a submission is received by CVM’s Document Control Unit (DCU).

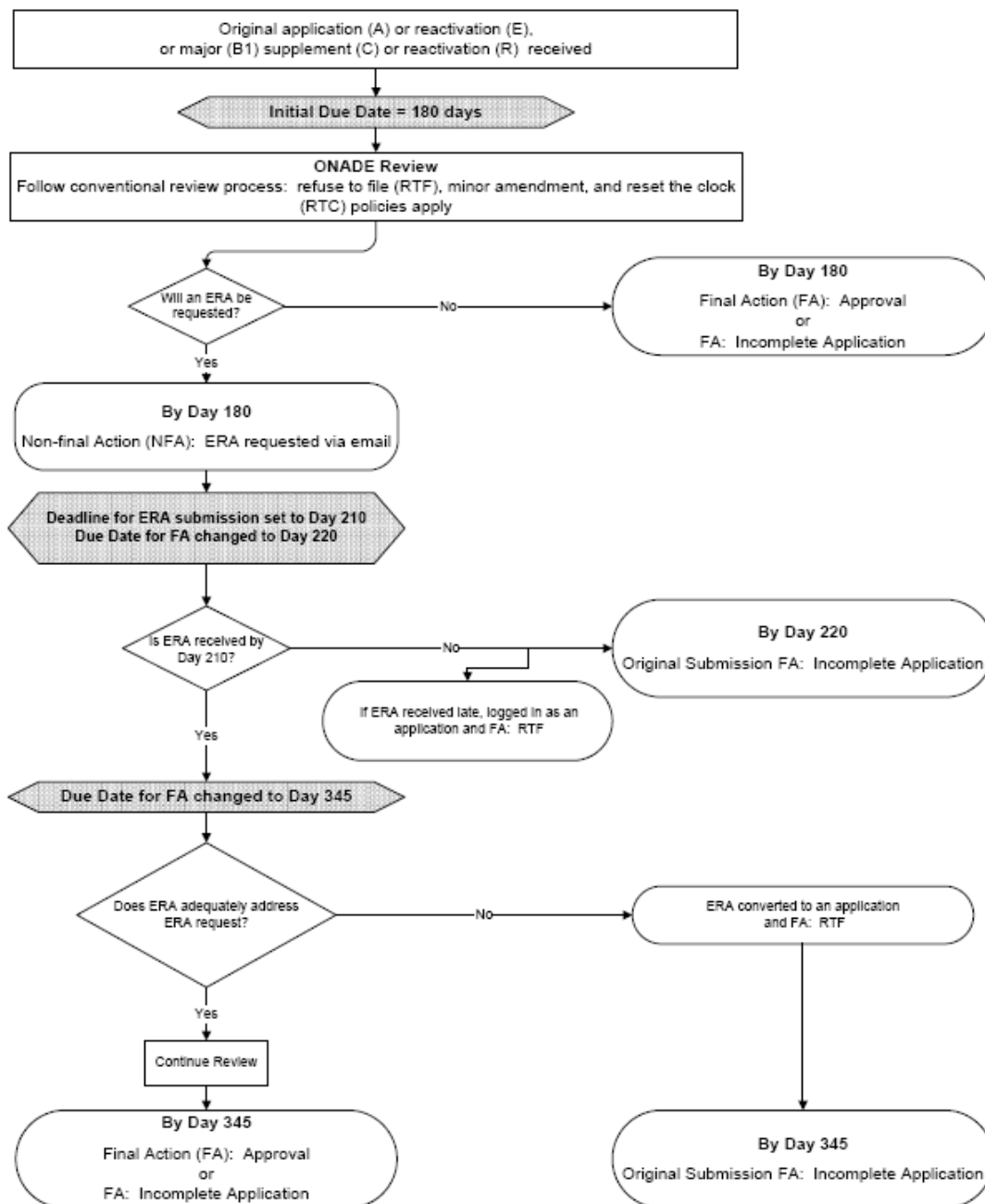
If we request an ERA and we receive it by Day 210, then the ADUFA deadline for completing the review of the application, incorporating the ERA, is 345 days.

The Goals Letter language pertaining to the performance goals for NADAs is in [Appendix 1](#).

III. ERA PROCESS FLOWCHART

The following flowchart shows the review process for NADAs, including key ADUFA deadlines, as it relates to the ERA.

**End Review Amendment Process:
Non-administrative NADAs and Non-manufacturing Supplements**



IV. KEY DATES

The following are key dates in the review of NADAs. The following have to occur on or before the indicated day:

Day 30 – Refuse to file, if applicable³

Day 180 – Three options:

1. Final action (FA) – Incomplete Application (FA Code 024: INC APP)
2. FA – Approval (FA Code 056: ORG APP LD; FA Code 051: SUP SIG LD)
3. Non-final action (NFA) – ERA Request (NFA Code 077: ERA REQSTD)

Day 210 – ERA submission must be received from sponsor

Day 220 – If ERA not received by Day 210: FA – Incomplete Application (FA Code 024: INC APP)

Day 345 – If ERA received by Day 210, two options:

1. FA – Incomplete Application (FA Code 024: INC APP)
2. FA – Approval (FA Code 056: ORG APP LD; FA Code 051: SUP SIG LD)

V. REVIEW OF NADAS UP TO DAY 180

The review of NADAs should follow conventional division review procedures, including refuse to file (RTF), reset the clock (RTC), and minor amendment procedures, before the first ADUFA deadline of Day 180.^{4 5}

³ Within 30 days of submission, FDA will refuse to file a new animal drug application which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110.

⁴ See P&P 1243.2050.

⁵ See P&P 1243.3026.

A. NADA Timeline

The project team for the NADA consists of the primary reviewer (PR), all the consulting reviewers, and an assigned project manager (PM). In conjunction with the primary and consulting review groups, the PM develops a timeline for the NADA review (NADA timeline). This timeline includes interim key dates, such as the dates by which consulting reviews are completed (including comments on labeling and Freedom of Information Summary), ERA-related key dates, and the date by which the approval package is sent for administrative review (if the application can be approved).

B. Communication

Communication is essential among the project team (PR, consulting reviewers, and the PM). The PM sets up periodic status checks (emails, phone calls, meetings, etc.) with the project team, as noted in the NADA timeline, during the application review. Because of the potential complexity of NADAs, the PM is the main point of contact for the project team.

If any reviewer wants a minor amendment, the reviewer should contact the PM, who coordinates with the project team to minimize individual amendment requests to the sponsor. All the project team members are responsible for informing the PM immediately if they run into an issue that may make the application unapprovable.

C. Reviews

All primary and consulting reviews throughout the review process need to be complete (i.e., signed and on yellow paper) according to the NADA timeline, whether or not an ERA is requested. The primary reason reviews need to be complete prior to the request for the ERA is because the ERA is a formal process that is linked to the ADUFA II performance goals. Thus, ERA request emails issued by CVM during this process have the same significance as letters signed by the division directors and team leaders. Therefore, all reviewers must complete their reviews according to the NADA timeline.

In addition to the formal nature of the ERA process, there are logistical issues that mandate completed reviews. For example, with applications, if we do not receive a requested ERA by Day 210, we must issue the incomplete letter for the

application by Day 220. This very short timeline necessitates that the PR have all completed reviews in order to process the letter administratively.

1. Consulting reviews are due by the date indicated in the NADA timeline.

The completed review includes the consulting reviewer's recommendation: (1) incomplete the application, (2) approve the application, or (3) request an ERA. If a consulting reviewer recommends an ERA, then the consulting review provides specific comments for the ERA request in the Transmit to Sponsor section of the review. (For definition and scope of an ERA request, please see [Appendix 2](#).)

The consulting review file name contains the submission number and the alphanumeric designation of the consulting review, followed by “.rev”. (Please see [Appendix 3](#) for file-naming conventions.) For example, a biometrics A1 consulting review for application A0000 is named “A0000a1b.rev”.

Return the consulting review to the PR using current procedures.⁶

2. The PR, in consultation with their team leader and the consulting reviewers as needed, evaluates the recommendations from the primary review and all consulting reviews to determine the appropriate final action or non-final action (i.e., ERA request). The PR documents the final decision in both the Submission Summary and Conclusions sections of the primary review.
3. The primary review is due by the date indicated in the NADA timeline.

The completed review includes the PR's recommendation: (1) incomplete the application, (2) approve the application, or (3) request an ERA. If the PR recommends an ERA, the review provides the PR's specific comments for the ERA request in the Transmit to Sponsor section of the review. (For definition and scope of an ERA request, please see [Appendix 2](#).)

The primary review file name contains the submission number and the 3-letter identifier of the review type, followed by “.rev”. (Please see [Appendix 3](#) for file-naming conventions.) For example, the review for application A0000, containing both effectiveness and safety data, is named “A0000esd.rev”.

⁶ See P&P 1243.3029.

The PR notifies the entire project team of the final decision (application can be approved, application incomplete, or ERA request).

If requesting an ERA, the PR does not return the submission jackets to DCU at this time. The PR sends the electronic copy of the PR review to the mailbox “CVM ONADE Records” for archiving, but keeps the hardcopies of the PR review and the consulting reviews.⁷

VI. FINAL ACTION OR ERA DECISION (BY DAY 180)

A. Application Approvable

If we can approve the application, the primary review division prepares an approval package using current procedures, and we approve the application by Day 180 (FA Code 056: ORG APP LD; FA Code 051: SUP SIG LD).^{8 9}

B. Application Incomplete

If the application is incomplete, the primary review division prepares a final action package using current procedures, and we issue an incomplete letter to the sponsor by Day 180 (FA Code 024: INC APP).¹⁰

C. ERA Request

If we are requesting an ERA, the PR prepares the ERA request email to the sponsor using the Transmit to Sponsor comments from the primary and consulting reviews. (Use the ONADE “NADA ERA Request” email template on your computer. The PR uses the boilerplate language provided in the template to request an update to the All Other Information (AOI) technical section.) The division director or team leader sends the ERA request email to the sponsor by Day 180.

Note: The ERA request email cannot have any attachments. All information transmitted to the sponsor must be contained within the body of the email.

⁷ See P&P 1243.3030.

⁸ See P&P 1243.3800.

⁹ For more information on how to use ONADE templates for emails and letters, please see the ONADE Tools Manual.

¹⁰ See P&P 1243.3030.

VII. ERA REQUEST

A. ERA Request Email

We send the ERA request via email to the sponsor by Day 180.¹¹ The division director or team leader sends the email via a division mailbox set up for the sole purpose of sending ERA-related email to sponsors. The email is addressed to the person who signed the cover letter or as directed by the sponsor, with a cc to the DCU mailbox “CVM_ONADE_NOTICE_DCU”.

The ERA is due by Day 210.

B. Email Documentation

Because the ERA email is an electronic letter to the sponsor, the primary review division prints a copy of the ERA email on pink paper for inclusion in the final action package (behind the final action letter) as a stand-alone document, and an electronic copy is saved as described below.

- The ERA request email file name contains the application number and the 3-letter identifier of the review type, followed by “-notice”. (Please see [Appendix 3](#) for file-naming conventions.) For example, the ERA request for application A0000, containing both effectiveness and safety data, is named “A0000esd-notice.htm”. To save an email in OUTLOOK, click on File/Save As within the opened email, choose the location to which it will be saved, choose the type of file (save as HTML [* .htm]), then click “Save”.

The primary review division sends the electronic file of the ERA request email to the DCU Mailbox “CVM ONADE Records” for archiving.

C. New ADUFA Deadline

The DCU enters the ERA request date into STARS when the DCU mailbox “CVM_ONADE_NOTICE_DCU” receives the cc of the ERA request email. This

¹¹ If we send the ERA request after Day 180, we miss the ADUFA deadline of 180 days for the non-final action. Although we miss the ADUFA deadline of 180 days for the ERA request, we continue with the review process. The due date for receipt of the ERA is still 30 days from the time of the ERA request. If the ERA is not received on time, the ADUFA deadline for the application is still 220 days. If the ERA is received on time and acceptable, the ADUFA deadline for the application is still 345 days.

triggers a new ADUFA deadline of 220 days for the application. Please note that DCU does not generate a new cover sheet for the application. Reviewers should refer to the STARS Pending Reviews screens and the NADA timeline for the new ADUFA deadline.

VIII. ERA NOT RECEIVED BY DAY 210

A. Incomplete the Application

If we do not receive the requested ERA by Day 210, or the sponsor notifies us that they will not be submitting an ERA, the application remains incomplete and we issue an incomplete letter.

1. The PR documents that we did not receive the ERA by Day 210 in a review. The review is limited to stating that we did not receive the ERA by Day 210, and that we will issue an incomplete letter for the application.

The title of the review should reflect the type of review written, followed by “ - ERA”.¹²

The review file name contains the application number and the 3-letter identifier of the review type, followed by “-no_era.rev”. (Please see [Appendix 3](#) for file-naming conventions.) For example, the review documenting that we did not receive the requested ERA for application A0000, containing both effectiveness and safety data, by Day 210 is named “A0000esd-noera.rev”.

2. The primary review division prepares a final action package using current procedures, and we issue an incomplete letter to the sponsor by Day 220. (Use the boilerplate language in [Appendix 4](#) for the incomplete letter when we do not receive an ERA by Day 210.) The incomplete letter should be a copy-and-paste from the ERA request email, which already details the reasons the application remains incomplete.

B. Refuse to File the ERA if Received Late

If we receive the requested ERA but it arrives after Day 210, we do not review it. Because we cannot administratively RTF an amendment (M, S, T, or U

¹² See P&P 1243.3009.

submission), the DCU automatically logs in the late ERA as a new submission of the parent submission type – in this case, as an application. We consider the ERA/application insufficient for review on its face, and we issue an RTF letter to the sponsor for the ERA/application. (Use the ONADE “ERA-RTF ltr” template on your computer.)

IX. ERA RECEIVED BY DAY 210

A. New ADUFA deadline

If we receive the requested ERA by Day 210, receipt of the ERA in the DCU triggers a new ADUFA deadline for the application (345 days) in STARS. Please note that the DCU does not generate a new cover sheet for the application. Reviewers should refer to the STARS Pending Reviews screens and the NADA timeline for the new ADUFA deadline.

B. Consulting Review Requests

The PR sends out consulting requests for the ERA. The PR should use informed discretion in deciding which consulting reviewers need to review the ERA. Not all reviewers consulted for the original review may need to be consulted for the ERA, but the PR should realize that the information in the submitted ERA might impact a consulting reviewer’s original conclusion(s). If there is any question, the PR should discuss the issue with the consulting reviewers.

When sending the consulting requests for the ERA, the PR should also send the jackets from the parent application in case the consulting reviewers need to refer back to the previously reviewed information. The PR should use the existing Review Request and Movement Form to move the jackets back through the DCU to the appropriate consulting reviewer. In the “For Reviewer’s Use” box, the PR should write that the jackets are being re-issued to the consulting reviewer for review of an ERA. The DCU will assign the appropriate package indicator (A1, B1, etc.) in the upper right-hand corner of the form.

C. Assessment of ERA

The PR and all consulting reviewers determine whether the ERA is acceptable for review within the timeframe indicated in the NADA timeline and as described below.

The PR and the consulting review divisions do an initial assessment of the information contained in the ERA to determine that (1) it appears to provide information on all the ERA-requested items and (2) it does not provide significant additional information beyond the scope of the ERA request.¹³ The ERA has to meet both conditions or it is not acceptable for review. This is a basic screen to determine if the ERA is acceptable for review; it is not a thorough review of the information to determine the acceptability of the data to support approval.

The consulting reviewers email the PR their conclusions that either (1) the submitted ERA does not address the ERA request, including the reasons why the ERA is not acceptable for review by the consulting reviewer, or (2) the ERA is acceptable for review by the consulting reviewer.

An ERA is not acceptable for review if one or more review groups makes that determination. Therefore, while some review groups may find the ERA acceptable for review from their perspective, we may determine that the ERA is unacceptable for review overall.

X. ERA NOT ACCEPTABLE FOR REVIEW

If the ERA is not acceptable for review, the following actions occur:

A. Consulting Requests Returned

The consulting reviewers return consulting requests for the ERA and the jackets from the parent application to the PR within 14 days of the decision.

B. ERA Converted

We do not review an ERA that is not acceptable for review. Because we cannot administratively RTF an amendment (M, S, T, or U submission), the PR converts the ERA to a new submission of the parent submission type (A, C, R, or E submission) using the STARS Correction Request Form. We issue an RTF letter

¹³ In the ERA request, we ask the sponsor to state that there is no additional information pertaining to safety or effectiveness in the AOI technical section. If there are new data or information, we request that they contact us before submission of the ERA so that we can determine whether the ERA process remains applicable. If a sponsor submits unsolicited significant new data or information in the AOI technical section of the ERA, this may render the ERA unacceptable for review.

to the sponsor for the converted ERA/application. (Use the ONADE “ERA-RTF ltr” template on your computer.)

C. Application Incomplete

1. The PR completes a review that cites the unacceptability of the submitted ERA as the basis for incompleting the application. The PR includes the emails from the consulting reviewers in the administrative record.

The title of the review should reflect the type of review written, followed by “ - ERA”.

The review file name contains the submission and the 3-letter identifier of the review type, followed by “-era.rev”. (Please see [Appendix 3](#) for file-naming conventions.) For example, the review documenting that the ERA for application A0000, containing both effectiveness and safety data, was unacceptable is named “A0000esd-era.rev”.

2. The primary review division prepares a final action package using current procedures, and we issue an incomplete letter to the sponsor for the application by Day 345. (Use the boilerplate language in [Appendix 4](#) for the incomplete letter when the ERA is not acceptable for review.) The incomplete letter should be a copy-and-paste from the ERA request email, which already details the reasons the application remains incomplete.

XI. ERA ACCEPTABLE FOR REVIEW

If the ERA is acceptable for review, the PR and the consulting reviewers review the ERA. There is only one ERA allowed for an application; we cannot request any subsequent ERAs during review of the submitted application.¹⁴ Additional minor amendments (e.g., labeling changes that were impacted by ERA information) are allowed.

A. Consulting Reviews

ERA consulting reviews are due by the date indicated in the NADA timeline.

¹⁴ If the application is incomplete and the sponsor reactivates the application, an ERA may be requested for the reactivation.

The ERA consulting review does not encompass the entire application; that is, it does not re-review the information originally submitted. The ERA review incorporates this information by referencing the previous consulting review. The ERA consulting review is limited to a review of the submitted ERA. The review should answer the question as to whether the ERA gives us the information we need to approve the application.

The consulting review includes the consulting reviewer's recommendation: (1) incomplete the application or (2) approve the application.

The title of the review should reflect the type of review written, followed by “ - ERA”.

The ERA consulting review file name contains the application number and the alphanumeric designation of the consulting review, followed by “-era.rev”. (Please see [Appendix 3](#) for file-naming conventions.) For example, the biometrics D1 consulting review of the ERA for application A0000 is named “A0000d1b-era.rev”.

Return the consulting review and the jackets from the parent application to the PR using current procedures.

B. Outcome of ERA Review

The PR, in consultation with the team leader and the consulting reviewers as needed, evaluates the recommendations from the primary ERA review and all consulting ERA reviews to determine the appropriate final action: (1) incomplete the application or (2) approve the application. The PR documents the final decision in both the Submission Summary and Conclusions sections of the primary review.

C. Primary Review

The primary review of the ERA is due by the date indicated in the NADA timeline.

The primary ERA review does not encompass the entire application; that is, it does not re-review the information originally submitted. The ERA review will incorporate this information by referencing the previous review. The ERA review will be limited to a review of the submitted ERA. The review should answer the

question as to whether the ERA gives us the information we need to approve the application.

The completed review includes the PR's recommendation: (1) incomplete the application or (2) approve the application.

The title of the review should reflect the type of review written, followed by "- ERA".

The review file name contains the submission number and the 3-letter identifier of the review type, followed by "-era.rev". (Please see [Appendix 3](#) for file-naming conventions.) For example, the review of the ERA for application A0000, containing both effectiveness and safety data, is named "A0000esd-era.rev".

XII. APPLICATION FINAL ACTION AFTER ERA REVIEW (BY DAY 345)

There are two possible final actions for the application:

A. Application Approvable

If we can approve the application after submission of the ERA, the primary review division prepares an approval package using current procedures, and we approve the application by Day 345.

- FA – Approval (FA Code 056: ORG APP LD; FA Code 051: SUP SIG LD)

B. Application Incomplete

If the application remains incomplete after submission of the ERA, the primary review division prepares a final action package using current procedures, and we issue an incomplete letter to the sponsor by Day 345.

- FA – Incomplete Application (FA Code 024: INC APP)

XIII. REFERENCES

ADUFA II Goals Letter

CVM Program Policy and Procedures Manual

1243.2050 – Refuse to file and refuse to review

1243.3009 – Format and style conventions for reviews and submission summaries

1243.3026 – Amending STARS submissions

1243.3029 – Closing out a consulting review for STARS submissions

1243.3030 – Completing final action packages for STARS submissions

1243.3800 – Preparing and processing an approval package

XIV. VERSION HISTORY

September 19, 2008 – original version

APPENDIX 1. ADUFA II GOALS LETTER LANGUAGE – NON-ADMINISTRATIVE NADAS AND NON-MANUFACTURING SUPPLEMENTAL NADAS**1. Non-administrative Animal Drug Applications**

- a. The Agency will review and act on 90 percent of non-administrative animal drug applications and reactivations of such applications within
 - i. 180 days after the submission date (Day 180) if the Agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or
 - ii. 220 days after the submission date if the Agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or
 - iii. 345 days after the submission date if the Agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.
- b. The end-review amendment procedure is not intended to prevent the use of minor amendments during Agency review of an animal drug application

4. Non-manufacturing Supplemental Animal Drug Applications

- a. The Agency will review and act on 90 percent of non-manufacturing supplemental animal drug applications (i.e. supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within
 - i. 180 days after the submission date (Day 180) if the Agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or
 - ii. 220 days after the submission date if the Agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or
 - iii. 345 days after the submission date if the Agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.
- b. The end-review amendment procedure is not intended to prevent the use of minor amendments during Agency review of a supplemental new animal drug application....

APPENDIX 2. DEFINITION AND SCOPE OF ERA REQUESTS

CVM proposed the ERA process during ADUFA II negotiations, in response to discussions on multiple review cycles. CVM made a good faith commitment to use this ERA process, when possible, with the goal of obtaining a complete review decision in one cycle.

Sponsors are expected to submit high quality submissions to facilitate review by the Office of New Animal Drug Evaluation (ONADE). Reviewers should follow the policies regarding refuse to file and refuse to review to determine if a submission can reasonably be reviewed. Once ONADE determines that a submission is acceptable for filing or review, both the minor amendment and ERA tools are available for use to facilitate completing the submission.

Reviewers should follow the policies regarding minor amendments during the course of their review. For example, if the reviewers deem an application approvable on the first review cycle, the reviewers should work with the sponsor to make needed label changes under the existing minor amendment process. Other examples of minor amendments are found in P&P 1243.3030.

Reviewers should communicate with sponsors as needed during the review process to obtain clarification or other information to facilitate the review.

Reviewers should consider all of the following factors in the decision to request an ERA. Request an ERA if:

- We can clearly identify and communicate to the sponsor the changes and/or submission of additional information that can complete the submission.
- We can complete review of the ERA submission and make the review decision in the time allotted. This decision should be based solely on the nature of the required changes/additional information.
- All consulting reviews and the primary review, when taken as a whole, support the decision to request the ERA.

APPENDIX 3. FILE-NAMING CONVENTIONS
Table 1. Application review types and their 3-letter file identifiers

Review Type	3-Letter File Identification
Combination Effectiveness and Safety	esd
Effectiveness	efd
FOI Summary	foi
Labeling	lab
Target Animal Safety	tsd

Table 2. Era-related documents and their file identifiers

Document Type	File identifier after submission ID
Initial review	None
ERA request email	-notice
ERA-related application reviews:	
No ERA submitted	-no_era
ERA submitted (both ERA not acceptable and ERA acceptable)	-era

APPENDIX 4. BOILERPLATE LANGUAGE FOR INCOMPLETE LETTER – NO ERA SUBMITTED BY DAY 210 OR ERA NOT ACCEPTABLE FOR REVIEW

Insert the following paragraph in the Division NADA Incomplete letter:

“We requested an end-review amendment (ERA) for this [supplemental] application. [Because we did not receive an ERA by <Month Day, 20XX>] **OR** [Because your ERA was not acceptable for review], the application remains incomplete. The following are the items requested for the ERA, and which make the application incomplete:”