INTEGRATING AN END-REVIEW AMENDMENT (ERA) INTO THE INVESTIGATIONAL NEW ANIMAL DRUG DATA (P) SUBMISSION REVIEW PROCESS

I. PURPOSE

This document describes the procedures for:

- Integrating an end-review amendment (ERA) into the investigational new animal drug (INAD) data (P) submission review process.

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 INAD data (P) submissions.

The ADUFA II Goals Letter states, "The term 'end-review amendment (ERA)' is understood to mean an amendment to an … investigational animal drug submission 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 … submission. This term does not include minor amendments that are requested by CVM during review of … submissions …."

There are different performance goals (i.e., ADUFA deadlines) for the review of data submissions, based on whether we request an ERA and whether we receive a requested ERA on time.

If we consider a data submission complete (i.e., acceptable to support approval), the ADUFA deadline for completing the review of the submission is 180 days.[1] [2]

If we do not consider a data submission complete based on the submitted information and we do not request an ERA, the ADUFA deadline for completing the review of the submission is 180 days.

If we determine that an ERA would likely allow us to complete a review of the data submission and reach a decision on whether the submission is acceptable to support approval, 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 data submission (without the ERA) is 220 days.

If we request an ERA and we receive it by Day 210, then the ADUFA deadline for completing the review of the data submission, incorporating the ERA, is 270 days.

The Goals Letter language pertaining to the performance goals for data submissions is in Appendix 1.

[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) notifies a sponsor that an investigational animal drug submission is complete or (2) sets forth in detail the specific deficiencies in the submission and, where appropriate, the actions necessary to place the submission in condition for approval.

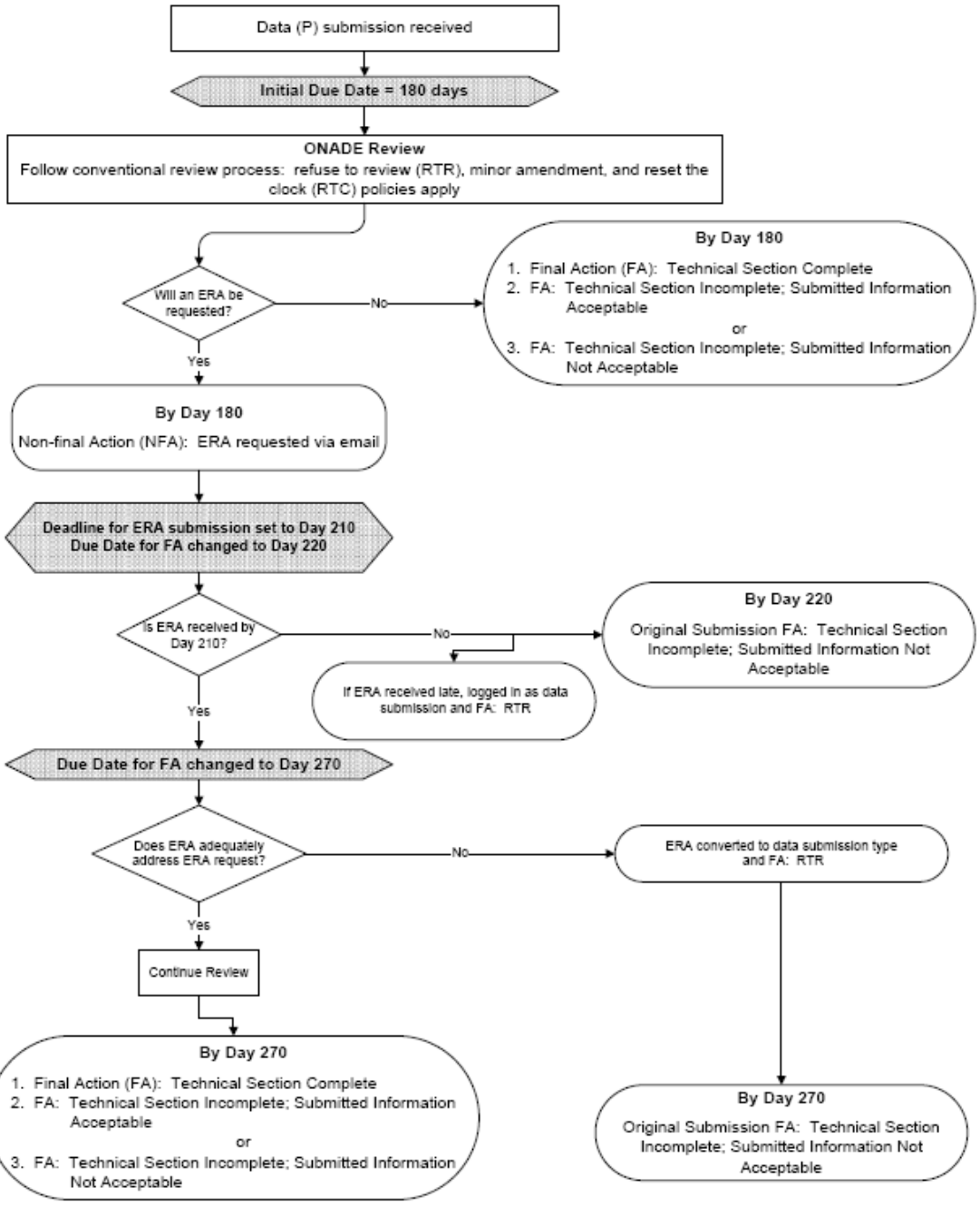
[2] Unless otherwise stated, all timeframes reference the date that a submission is received by CVM's Document Control Unit (DCU).

III. ERA PROCESS FLOWCHART

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

End Review Amendment Process:

Data (P) Submissions



IV. KEY DATES

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

Day 60 – Refuse to Review, if applicable[3]

Day 180 – Four options:

1. Final action (FA) – Technical Section Incomplete; Submitted Information Not Acceptable (FA Code 201: TS INC NOT)

2. FA – Technical Section Incomplete; Submitted Information Acceptable (FA Code 203: TS INC OK)

3. FA – Technical Section Complete (FA Code 202: TS COMPLTE)

4. 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 – Technical Section Incomplete; Submitted Information Not Acceptable (FA Code 201: TS INC NOT)

Day 270 – If ERA received by Day 210, three options:

1. FA – Technical Section Incomplete - Submitted Information Not Acceptable (FA Code 201: TS INC NOT)

2. FA – Technical Section Incomplete - Submitted Information Acceptable (FA Code 203: TS INC OK)

3. FA – Technical Section Complete (FA Code 202: TS COMPLTE)

[3] Guidance for Industry #119 and ADUFA II Goals Letter: Within 60 days of submission, FDA will refuse to review (RTR) an INAD submission which is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110.

V. REVIEW OF DATA SUBMISSIONS UP TO DAY 180

The review of data submissions should follow conventional division review procedures, including refuse to review (RTR), reset the clock (RTC), and minor amendment procedures, before the first ADUFA deadline of Day 180.[4] [5]

A. Data Submission Timeline

A project manager (PM) creates the timeline and posts it in a central location for everyone on the review team to access. The primary reviewer (PR) and any consulting reviewers follow the timeline developed for data submission review (submission timeline). This timeline includes interim key dates, such as the date by which the PR finalizes the database with the Biostatistics team, the dates by which consulting reviews are completed, and ERA-related key dates.

B. Communication

Communication is essential among the review team members (PR and consulting reviewers). If any reviewer wants a minor amendment, the reviewer should contact the PR, who coordinates with the review team to minimize individual amendment requests to the sponsor. All the review team members are responsible for informing each other immediately if they run into an issue that may make the submission incomplete.

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 submission 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 submission timeline.

In addition to the formal nature of the ERA process, there are logistical issues that mandate completed reviews. For example, with data submissions, if we do not

[4] See P&P 1243.2050.
[5] See P&P 1243.3026.

receive a requested ERA by Day 210, we must issue the incomplete letter for the submission 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 submission timeline.

   The completed review includes the consulting reviewer's recommendation: (1) incomplete the submission, (2) complete the submission, or (3) request an ERA. If the 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, followed by the 2-character alphanumeric designation of the consulting review, the 1-letter identifier for the consulting review topic, and ".rev". (Please see Appendix 3 for file-naming conventions.) For example, the biostatistics A1 consulting review for submission P0019 is named "P0019a1b.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 submission timeline.

   The completed review includes the PR's recommendation: (1) incomplete the submission, (2) complete the submission, 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 PR should handle the Freedom of Information (FOI) Summary and labeling submitted as part of the P submission as per current division policy

[6] See P&P 1243.3029.

(i.e., discuss labeling/FOI Summary with the sponsor prior to completing the review if it makes sense to do so).

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 target animal safety study data submission P0019 is named "P0019tsd.rev".

The PR notifies the entire review team of the final decision (i.e., submission complete, submission 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 primary review to the mailbox "CVM ONADE Records" for archiving, but keeps the hardcopies of the primary review and the consulting reviews.

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

A. Submission Complete

If the submission is complete, that is, acceptable to support approval, the primary review division prepares a final action package using current procedures, and we issue the appropriate letter (Technical Section Incomplete, Submitted Information Acceptable; or Technical Section Complete) to the sponsor by Day 180 (FA Code 203: TS INC OK; FA Code 202: TS COMPLTE).[7] [8]

B. Submission Incomplete

If the submission 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 201: TS INC NOT).

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 Data Submission ERA Request email template on your

[7] See P&P 1243.3030.
[8] See P&P 1243.4080.

computer.[9]) The division director or team leader sends the ERA request email to the sponsor by Day 180.

If the sponsor has submitted all required major technical sections and the corresponding minor technical sections (Labeling and All Other Information [AOI]), the PR includes the language provided in the ERA request email template regarding amending the AOI minor technical section.

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

VII. ERA REQUEST

A. ERA Request Email

We send the ERA request via email to the sponsor (NFA Code 077: ERA REQSTD) by Day 180.[10] 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 email is an electronic letter to the sponsor, the primary review division saves an electronic copy of the sent email and prints a copy on pink paper for inclusion in the final action package (behind the final action letter) as a stand-alone document, as described below.

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

[10] 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 submission is still 220 days. If the ERA is received on time and acceptable, the ADUFA deadline for the submission is still 270 days.

- The archived version of the email is the version that was actually sent to the sponsor (i.e., the version that appears in the Sent Items folder in OUTLOOK).

- The ERA request email file name contains the submission 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 target animal safety study data submission P0019 is named "P0019tsd-notice.pdf".

- To save the email as a PDF file, open the email from the Sent Items folder in OUTLOOK. From the File menu of the opened email, choose "Print...". In the Print dialogue box that appears, choose Adobe PDF as the printer, ensure that all pages will print and only one copy will print, and click "Print." When prompted, select the location to save the email (according to division policy), type in the file name as directed in the bullet above, and click "Save." A PDF file of the email will be saved in the selected location and will appear in a new window. This process may take a few minutes, depending on your computer.

- Print the PDF copy of the email on pink paper for inclusion in the final action package.

The primary review division sends the electronic PDF 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 triggers a new ADUFA deadline of 220 days for the submission. Please note that DCU does not generate a new cover sheet for the submission. Reviewers should refer to the STARS Pending Reviews screens and the submission timeline for the new ADUFA deadline.

VIII. ERA NOT RECEIVED BY DAY 210

A. Incomplete the Submission

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 submission remains incomplete and we issue a technical section 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 data submission.

   The title of the review should reflect the type of review written, followed by " - ERA".[9]

   The review file name contains the submission 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 ERA within 10 days of the request for target animal safety study data submission P0019 is named "P0019tsd-no_era.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 submission remains incomplete.

B. Refuse to Review 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 RTR an amendment (T submission), the DCU automatically logs in the late ERA as a new submission of the parent submission type – in this case, as a data (P) submission. The ERA/data submission is considered to be insufficient for review on its face, and we issue an RTR letter to the sponsor for the ERA/data submission. (Use the ONADE "ERA-RTR ltr" template on your computer.)

[9] See P&P 1243.3009.

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 submission (270 days) in STARS. Please note that the DCU does not generate a new cover sheet for the submission. Reviewers should refer to the STARS Pending Reviews screens and the submission timeline for the new ADUFA deadline.

NOTE: The PR and all consulting reviewers add the date we receive the ERA into the submission timeline so that the timeline accurately reflects all of the due dates.

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 original data submission. The PR will prepare a new Review Request and Movement Form and staple it on top of 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 of the new form, 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 submission 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. The ERA needs 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 original data submission 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 RTR an amendment (T submission), the PR converts the ERA to a new submission of the parent submission type using the STARS Correction Request Form. In this case, the PR converts the unacceptable ERA to a data (P) submission. We issue an RTR letter to the sponsor for the converted ERA/data submission. (Use the ONADE "ERA-RTR ltr" template on your computer.)

C. Submission Incomplete

1. The PR completes a review that cites the unacceptability of the submitted ERA as the basis for incompleting the submission. 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 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 documenting that the ERA for target animal safety study data submission P0019 was unacceptable is named "P0019tsd-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 submission by Day 270. (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 submission 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 a submission; we cannot request any subsequent ERAs during review of the submission. Additional minor amendments are allowed.

A. Impact of last pending major technical section data submission

The due dates for the minor technical section (M) submissions and the FOI Summary (Q) submission are linked to the due date for the last pending data (P) submission. Working closely with the review team and the sponsor, the Program Manager (PM) will create a detailed "end-game" timeline to ensure the optimal time for the sponsor to submit the M submissions and related tasks. The PM will look at the pending P submissions across divisions and communicate with the PR to ensure that any pending M submission references the correct P submission.

If we request and receive an ERA for the last pending P submission, the DCU automatically resets the due date for any pending M submission referencing that P submission.

If we request and receive an ERA for a pending P submission that now becomes the last pending P submission because of the new ERA deadline, the primary

review division submits a STARS Correction Request form to ensure that the M submissions now reference and have the same due date as the P submission. The primary review division should request a similar change in due date for the pending Q submission.

If requested in the ERA email, the sponsor should submit an amendment to the AOI minor technical section submission. The primary review division should ensure that this amendment references the correct P submission.

B. Consulting Reviews

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

The ERA consulting review does not encompass the entire data submission; that is, it does not re-review the information originally submitted. The ERA review will incorporate this information by referencing the previous consulting review. The ERA consulting review will be limited to a review of the submitted ERA. The review should determine whether the ERA gives us the information we need to complete the submission; that is, accept the submission as supporting approval.

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

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

The ERA consulting review file name contains the submission number, followed by the 2-character alphanumeric designation of the consulting review, the 1-letter identifier for the consulting review topic, and "-era.rev". (Please see Appendix 3 for file-naming conventions.) For example, the biostatistics D1 consulting review of the ERA for data submission P0019 is named "P0019d1b-era.rev".

Return the consulting review and the jackets from the original data submission to the PR using current procedures.

C. 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 submission or (2) complete the submission. The PR documents the final decision in both the Submission Summary and Conclusions sections of the primary review.

D. Primary Review

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

The primary ERA review does not encompass the entire submission; 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 determine whether the ERA gives us the information needed to complete the submission; that is, accept the submission as supporting approval.

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

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 target animal safety study data submission P0019 is named "P0019tsd-era.rev".

XII. SUBMISSION FINAL ACTION AFTER ERA REVIEW (BY DAY 270)

There are two possible final actions for the submission:

A. Submission Complete

If the submission is complete after submission of the ERA, that is, it is acceptable to support approval, the primary review division prepares a final action package using current procedures, and we issue the appropriate complete letter to the sponsor by Day 270.

- FA – Technical Section Complete (FA Code 202: TS COMPLTE)

- FA – Technical Section Incomplete; Submitted Information Acceptable (FA Code 203: TS INC OK)

B. Submission Incomplete

If the submission remains incomplete after submission of the ERA, that is, it is not acceptable to support approval, the primary review division prepares a final action package using current procedures, and we issue an incomplete letter to the sponsor by Day 270.

- FA – Technical Section Incomplete; Submitted Information Not Acceptable (FA Code 201: TS INC NOT)

XIII. REFERENCES

ADUFA II Goals Letter

CVM Guidance for Industry

How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug (#119)

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

XIV. VERSION HISTORY

September 19, 2008 – original version

March 24, 2009 – Revised to clarify how to save the ERA email.

APPENDIX 1. ADUFA II GOALS LETTER LANGUAGE – DATA SUBMISSIONS

6. Investigational Animal Drug Study Submissions

a. The Agency will review and act on 90 percent of investigational animal drug study submissions within

   i. 180 days after the submission date (Day 180) if the Agency determines that the submission is complete or incomplete. A submission is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the study submission and reach a decision on the issue(s) presented in the submission; 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 submission and electronically requests an end-review amendment to the submission on or before Day 180, but the sponsor fails to submit such amendment on or before Day 210. If a sponsor submits an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (270 days) will not apply, and a complete action letter will be issued by Day 220 for the original submission; or

   iii. 270 days after the submission date if the Agency electronically requests an end-review amendment to the submission on or before Day 180 and the sponsor submits 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 study submission ….

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. Examples of minor amendments are found in P&P 1243.3026.

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. Data submission primary review types and their 3-letter file identifiers

Review Type	3-Letter File Identification
Bioequivalence	bqd
Combination Effectiveness and Safety	esd
Effectiveness	efd
Environmental	env
FOI Summary	foi
Human Food Safety – Analytical Methods	hsa
Human Food Safety – Genetox	hsg
Human Food Safety – Microbiological	hsm
Human Food Safety – Residue	hsr
Human Food Safety – Toxicology	hst
Human Safety – User Safety	hsu
Labeling	lab
Manufacturing	mfd
Manufacturing Chemistry	mcd
Microbiology	mic
Pharmacokinetic	pkd
Target Animal Safety	tsd

Table 2. Data submission consulting review topics and their 1-letter file identifiers

Review Type	1-Letter File Identification
Analytical Methods	a
Biostatistics	b
Environmental	e
Genetic Toxicology	g
Label	l
Manufacturing	m
Pharmacokinetics	p
Residue Chemistry	r
Safety and/or Effectiveness	s
Toxicology	t
Microbiology	u
External Consult	x

Table 3. Era-related documents and their file identifiers

Document Type	File identifier after submission ID
Initial review	None
ERA request email	-notice
ERA-related data submission 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 Technical Section Incomplete, Submitted Information Not Acceptable letter:

We requested an end-review amendment (ERA) for submission P-0000. [Because we did not receive an ERA by <Month Day, 20XX>] OR [Because your ERA was not acceptable for review], the submission remains incomplete. The following are the items that we requested for the ERA and cause the submission to be incomplete: