OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

VERIFYING SCOPE AND TECHNICAL SECTION STATUS FOR PHASED REVIEW PROJECTS IN THE END GAME

I. PURPOSE

This document explains how the Office of New Animal Drug Evaluation (ONADE) verifies the scope and technical section (TS) status for phased review projects in the end game. This document applies to:

- all investigational new animal drug (INAD), new animal drug application (NADA), or conditional approval (CA) projects that will culminate in original approvals, including Animal Drug Availability Act of 1996 (ADAA) combinations,[1] and
- INAD, NADA, CA, or abbreviated NADA (ANADA) projects that will culminate in supplemental approvals that require safety and/or effectiveness data (i.e., Category II supplements as described in 21 CFR 514.106(b)(2)).

II. BACKGROUND

A phased review project is considered to be in the end game when ONADE receives the last P submission. At this point, the project team meets (i.e., the end game meeting) to verify that the project scope is the same for all applicable major TSs, confirm the status of all applicable major TSs,[2] verify formulation information, and discuss any issues with the project and/or preparations for the approval. The project scope includes information relevant to the application; e.g., established name, dosage form, dose, duration, route of administration, species and class, and indication. The project team consists of the project manager (PM) and at least one representative from each team responsible for the review of each applicable major TS. TS status may be complete or pending.

[1] For 60-day ADAA procedures, refer to P&P 1243.5730.
[2] An applicable TS is a TS required for that project type; e.g., Human Food Safety is not an applicable TS for a companion animal project.

III. PROJECT TEAM PREPARES FOR THE END GAME MEETING

When ONADE receives the last P submission for a phased review project, the assigned PM creates a Q submission (per P&P 1243.3250) and assigns it to themselves, AFTER checking for the following issues.

- If any P submission is under review for this project and has a due date that is between when the last P submission was received and end game meeting date, the PM reaches out to the primary reviewer (PR) and asks if the TS is expected to be complete. If applicable, the PM also checks in Appian to see if there are any concerns noted in sub-consults that have been returned to a PR of an open TS before reaching out to that PR to inquire about the review status.
    - If there is a recent TS submission, the PM reaches out to the assigned reviewer to check on any known submission issues (i.e., refuse to review).
    - If the in-house P submission is expected to be complete, incomplete with shortened review timeframe (SRT) offered, or if the reviewer is unsure, the PM proceeds with the end game meeting procedure.
    - If the in-house P submission will be incomplete with no SRT offered, the PM does not proceed with the end game meeting procedure as the project will not remain in the end game. The PM documents in the Submission Tracking and Reporting System (STARS) Drug Development Projects (DDP) module that the end game meeting is not being held at this time because a TS is incomplete.
- Identify if the INAD is pursuing CA or expanded CA (XCA).

A. The PM Sends Consult Requests and Schedules the Meeting

1. The PM completes as much of the ONADE End Game Q template as they can in advance. The PM uses the information in that document to complete the PM teams' consult request template and populate the Outlook meeting invite. This gives the review teams the information they need to assign the consult appropriately and to prepare for the meeting.
2. The PM uses the PM teams' end game consult request template to request consults (see P&P 1243.3200).
    a. Using STARS, consult the reviewers representing each TS (and each Human Food Safety component). If there were a series of P submissions for one TS or component, consult the reviewer from the most recent submission. If the reviewer who worked on a TS is no longer with ONADE, send the consult to their team without requesting a specific reviewer.
    b. Consult the Clinical Pharmacology Team, regardless of whether they were involved in the review of submissions for the project (per SOP 1243.166.001), with the following exception: the Clinical Pharmacology Team does not need to be included in the end game meetings for ADAA combinations or Division of Animal Bioengineering and Cellular Therapies (DABCT) products.
3. After consults are assigned to reviewers, the PM schedules the meeting in Outlook. To create the Outlook meeting invite, the PM copies the completed table

about project scope and the completed project background information from the ONADE End Game Q template and adds them into the Outlook meeting invite.

a. The PM schedules the end game meeting no later than approximately 90 days into the review of the last 180-day P submission. The meeting is scheduled as a virtual meeting with a 30-minute duration.

b. The PM invites the following people to the meeting:

i. the consulted reviewers from the project team[3] and review team[4] with their team leaders (TLs) included as optional attendees;

ii. the Quality Assurance Team's quality control reviewers as optional attendees. The PM does not schedule around them; and

iii. anyone else who is important to the end game discussion. This may be, for example, an additional reviewer (with their TL included as optional), a member of the Policy Team, a science advisor, or anyone else whose input is critical to the outcome of the discussion.

4. After scheduling the meeting, the PM adjusts the due date of the Q submission through the Appian ONADE Update Q Submission Due Date workflow, if needed, and ensures that the consulting review(s) due date(s) is after the end game meeting is held.

B. Consulting Reviewers (CRs) Prepare for the Monthly Meeting by Confirming the Items Below

1. Whether the information in their TS is consistent with the project scope as identified by the PM in the consult request and the end game meeting invite.

2. Whether there have been any changes during the project that require reevaluation of TS requirements.

3. TS status (complete or pending, i.e., under review), and if complete, whether the determination is still valid.

4. Whether the drug product information (including formulation) utilized in target animal safety (TAS) and effectiveness (EFF) studies is consistent with information in the Chemistry, Manufacturing, and Controls (CMC) TS for the new animal drug product that will be approved.

   Note: For supplemental approvals, there are two exceptions where there is no test article information to verify. One exception is, if there are no TAS or EFF submissions (e.g., a supplement for an approved product that only affects the Human Food Safety (HFS) TS, or a new application for an ADAA feed-use combination). The second exception is if there is no CMC submission.

   a. For situations where the TAS and/or EFF TS is already complete, the Division of Manufacturing Technologies (DMT) reviewer follows the procedure

[3] A representative from each of the Office of New Animal Drug Evaluation's (ONADE) review teams responsible for the primary review of the applicable major technical sections.
[4] Includes the group working on a particular submission including all consultants.

described in ONADE SOP 1243.118.001, section III. B. At least 2 days before the end game meeting, the DMT reviewer emails the target animal division (TAD) reviewer and the PM noting whether they located the test article information in the appendix of the TAS and/or EFF TS reviews and/or a Formulation Information Sheet (this document was used prior to November 2021 and would live in Corporate Document Management System (CDMS) as either a stand-alone document or in the appendix of the TAS or EFF TS reviews).

i. If the test article information and/or Formulation Information Sheet is not available, the DMT reviewer coordinates with the TAD reviewer to obtain the test article information before the end game meeting. The DMT reviewer fills out the test article information template as described in the ONADE SOP 1243.118.001. If the CMC TS is already complete, the test article information is included in the End Game Q memo as an Other Review Related File. If the CMC TS is not complete, the test article information is included as an appendix to the CMC TS review.

b. If a TAS or EFF TS submission is open at the time of the end game meeting, the TAD reviewer fills out and send the completed Test Article Information template to the DMT reviewer and PM at least two (2) days before the end game meeting. The Test Article Information template is included as an appendix to the open TAS or EFF TS review.

c. If formulation changes or other issues with the test article are identified, the TAD and DMT reviewers discuss the implications prior to the end game meeting, if possible. If there is not time prior to the end game meeting, the issues are discussed at the end game meeting.

5. For full approvals only (not CAs), whether all proposed labeling in the submission includes the "Approved by FDA under NADA # XXX-XXX" statement required by September 30, 2023. If any proposed labeling does not, the TAD reviewer determines how to remind the sponsor. (Addition of statement to Blue Bird labeling is voluntary, but we are encouraging sponsors to add it.) For supplements, the TAD reviewer also determines if any previously approved and marketed labeling components identified in the NADA's Volume 0 do not include the new labeling statement and address how they will remind the sponsor to update that labeling (see ONADE Policy Initial Recommendations for the Addition of Approved by FDA Statements to Labeling).

IV. PROJECT TEAM HOLDS THE END GAME MEETING

The project team discusses the following items to identify issues that may impact the approval.

1. Review the project scope information, which is included in the meeting invite.

2. Verify whether the project scope is the same for each TS. Reviewers discuss whether there are any changes that have occurred in the project and if those changes would cause re-evaluation of any TS requirements.

3. Confirm the status of each TS (including the correct submission number(s)). Reviewers may identify TS status as complete or pending (i.e., under review).

a. For TSs that are complete, confirm whether the completed TS is still valid.

   i. If a TS is no longer considered complete, the reviewer(s) should specify if that is because the sponsor changed the scope of the project (the sponsor may opt to revert back to the original scope to leverage the completed TS), or because CVM no longer accepts the information submitted (the sponsor cannot leverage the completed TS regardless of scope). If the sponsor can amend their project scope to leverage a completed TS, the PM schedules an informal call with the reviewer(s) and the sponsor to discuss the sponsor's options. If CVM no longer accepts the completed TS, the division or team responsible for that TS creates a Q submission and issues a formal letter to notify the sponsor that the TS is no longer complete. The reviewer(s) discusses what the sponsor should do to satisfy the TS requirements during the end game meeting.

   Note: The procedures for updating a previously accepted claim of categorical exclusion under the Environmental Impact TS during the end game due to a change in the proposed conditions of use are described in a separate document.[5]

4. Confirm whether the formulation for the drug product utilized in TAS and EFF studies is consistent with the new animal drug product that will be approved. If needed, discuss the impact of any inconsistencies on the project.

5. For CAs: Confirm that the sponsor has submitted the correct P submission for the Environmental Impact TS in support of CA. At FDA, both a CA and full NADA approval are considered actions (21 CFR 514.1(b)(14)) that require separate Environmental Impact TSs (P submissions). Therefore, a separate Environmental Impact TS complete letter needs to be obtained prior to the CA, and again for the full approval.

6. For full approvals only (not CAs): Address the status of the "Approved by FDA under NADA # XXX-XXX" statement on all proposed labeling, including whether any additional labeling components need to be updated for supplements.

7. For DABCT products: Confirm whether the sponsor needs to complete establishment registration and drug listing approval of the NADA.

8. Identify whether the product is: 1) for use in a food-producing animal; and 2) contains an antimicrobial drug (regardless of medical importance)[6] or a drug intended as an alternative to traditional antimicrobials. Typically, this means applications where safety and/or effectiveness was evaluated, but some major non-fee (NF) supplements may be of interest. This information does not need to be provided for non-fee labeling (NL) supplements, most NF labeling supplements, or CMC supplements. When in doubt, provide the requested information to the ONADE Director (OD). After receipt of this information, the OD will determine whether to communicate further with others in CVM (e.g., the Center Director).

[5] Per SOP 1243.162.XXX DRAFT Reopening the Environmental Impact Technical Section and Reevaluating Claims of Categorical Exclusion in the End Game, notification that a categorical exclusion request must be resubmitted and is eligible for 60-day review can be issued under the end game Q submission.

[6] Except ionophores. It is not necessary to notify the ONADE Office Director prior to approval of ionophores.

If so, identify who will work with the PM on the content of the required antimicrobial informational email that is prepared using the ONADE Antimicrobial Alert email template and sent by the PM to the OD and Deputy OD.[7]

V. PROJECT MANAGER'S PROCESS FOR PREPARING AND REVIEWING THE END GAME MEETING DOCUMENT

The PM completes the ONADE End Game Q memo template to document the discussion that occurred at the end game meeting. If the product is confirmed in the meeting to be for use in a food-producing animal and to contain an antimicrobial or an alternative to traditional antimicrobials, the PM attaches a copy of the antimicrobial email alert in the specified appendix of the end game memo.

The PM sends the end game memo to their TL for first review; the TL reviews the memo before it goes to the review team, so any changes are made before the review team comments or concurs. After the PM receives feedback from their TL, they send the memo to the review team for comment and concurrence; the review timeframe is a week.

The PM documents review team comment or concurrence in the memo (each CR should return one concurrence on behalf of their team). The PM then sends the memo to their TL for final review before uploading into Appian. The PM adds a review summary to STARS as part of the Appian closeout. This should be a brief summary such as, "End game for trenbolone acetate and estradiol benzoate extended-release implants for increased rate of weight gain for up to 200 days in growing beef steers and heifers fed in confinement for slaughter."

VI. PROJECT MANAGER COORDINATES THE END GAME

The PM performs the following activities as part of managing the project during the end game.

1. Input all correspondence with the sponsor into the STARS DDP module.
2. Follow up with the sponsor:

   with any issues or questions regarding the project scope When applicable, correspondence may also be included as an appendix to the end game Q document;

   a. for CAs, ensure that the sponsor recognizes that they should start working on their Substantial Evidence of Effectiveness before obtaining their CA, because this could take longer than five years (per P&P 1243.5704); or

   b. if they have not submitted the All-Other Information (AOI) and Labeling minor TSs (M submissions) to coordinate the timing of the submissions (per P&Ps 1243.4085 and 1243.4080, respectively). Ideally, the sponsor submits these no later than 80 days after submission of the last P submission.

   c. Structured Product Labeling (SPL): A sponsor's name must be registered in accordance with the Code of Federal Regulations (CFR) 21 CFR 510.600.

[7] Also include the HFV-157 team leader (TL), the target animal division (TAD) reviewer, the TAD reviewer's TL, and the TAD reviewer's division director (DD) in the cc: line.

i. For a new sponsor without an approved (A)NADA, the PM will email the sponsor to remind them to request their registration by sending an email to the SPL group at Internal information redacted. Then, the PM will coordinate with the TAD and Policy Team to verify that the new sponsor is successfully registered under 21 CFR 510.600. A new sponsor's name won't appear under the CFR until the (A)NADA is approved.

ii. For a sponsor that has at least one approved (A)NADA, the sponsors firm name and address will appear under in 21 CFR 510.600 as a registered firm with a drug labeler code. No action is needed by the PM.

3. When the M submissions arrive, or earlier if requested by the TAD team, create the Freedom of Information (FOI) Summary Q submission, and assign it to the appropriate TAD team (see P&Ps 1243.5761 and 1243.5762).

   Note: Ensure the minor TSs (M submissions) have the same due date as the last P submission.

4. Ensure that the M submissions reference the last P submission in the STARS database. If the due date for the last P submission is extended, confirm that the due dates for the M submissions are extended as well, and update the due date for the FOI Summary Q submission. If there is more than one open P, be alert to any change that would affect which P has the later due date. If another submission becomes the last P through a reset the clock action, send an email to the EDSR Mailbox,[8] requesting that the M submissions are linked to the correct P submission (see P&Ps 1243.3026 and 1243.4080 for information on resetting the clock and M submissions, respectively). The subject line should be Linked Submission Change. The ONADE Business Informatics Team manages the mailbox. When the change in STARS has been made, the requestor will get a notification email from the EDSR Mailbox.

   Note: The PM will remind the project team about issuing the Appian notifications. The primary reviewer for the FOI Summary Q submission and the M submissions should notify the PM with an Appian notification when final action is taken.

5. Perform the Day 150 check-in process described in Section VII.

   Note: The PM provides a reminder to the project team at the end game meeting that the Day 150 check-in process will be followed if/when it applies.

6. If any TS is incomplete, notify the project team by email that the project is no longer in the end game. When the TS(s) are resubmitted, notify the project team through email that the project is once again in the end game. Determine with the project team whether another end game meeting is needed (e.g., it is advisable to meet again if the project is particularly complex or if a significant amount of time has elapsed since the previous end game meeting).

7. If a TS is incomplete and SRT is offered, and the P submission with SRT will be the last P submission, remind the sponsor to resubmit the M submissions at the same time as the TS resubmission (per P&P 1243.3060).

[8] Internal information redacted

8. When a TS is resubmitted that qualifies for SRT, verify that the M submissions were resubmitted at the same time and if they were not, remind the sponsor to submit them as soon as possible.

9. When the M submissions are resubmitted, create the FOI Summary Q submission in Appian and assign it to the appropriate TAD team.

10. If the M submissions are expected to go overdue, the PM or the TAD team notifies the sponsor and provide them with the new target due date (per P&P 1243.3026).

    Note: If the M submissions are expected to be submitted after all the major TSs are complete (i.e., there are no pending P submissions), the PM notifies the project team, and confirm that the M submissions reference the most recently completed P submission in STARS (per P&P 1243.4080).

11. Work with the project team and office leadership, as needed, in any center-level preparations needed for an approval, such as arranging for press releases or compliance actions (see SOP 1243.100.004).

12. If the sponsor requested to reserve an application number for a new animal drug (per 1243.3750), ensure that they know how to complete the eSubmitter NADA A 0000 template so that they do not receive another NADA number for their application.

13. Remind the sponsor to request their user fee waiver or make their payment and prepare their user fee cover sheet for the approval package to expedite their submission of the approval package.

VII. PROJECT TEAM COMPLETES THE DUE DATE MINUS 30 DAY CHECK-IN

At approximately 30 days prior to due date of the last P submission, the PM emails the PR for that P, the PR for any other currently pending Ps, and the PR for the M submissions, to request a status check and the planned finish date for the M submissions. For example, for a 180-day submission, this would take place at Day 150. For a shortened review submission, this would take place at Day 30.

If no issues have been identified that would merit an incomplete, the PM:

- sends an email to inform the full project team that the project is still on track; and
- updates the timeline and the estimated approval date in the STARS DDP module if the target completion date has changed for the M submissions.

If the PM learns that there is an issue with the P submission(s), the PM schedules a 30-minute meeting with the full project team to discuss:

- what the issue is (e.g., the P is incomplete, the clock is being reset);
- the plan for addressing the issue (e.g., amendment, reset the clock, TS incomplete (TSI), TSI SRT resubmission offered);
- how the M submissions will be handled based on the approach for the P submission; and
- how to communicate the plan to the sponsor, if applicable.

This check-in does not happen if the project is no longer in the end game at that point (e.g., another P has gone incomplete and has not yet been resubmitted). The PM only documents the check-in process in the STARS DDP module (i.e., no second end game Q document is needed for this purpose). If appropriate, the PM follows up with the project team or sponsor (as determined by the PM and their TL) based on the outcome of the check-in.

For a CA project, if the project is on track for approval, the PM follows up with the sponsor about requesting a meeting to discuss their post-CA responsibilities as described in P&P 1243.5706.

VIII. PRIMARY REVIEWER NOTIFICATIONS WHEN CLOSING M SUBMISSIONS AND FOI Q

The PR for the final P submission should notify the PM with an Appian notification when final action is taken on that submission. If the final P is assigned to HFV-140, HFV-150 or HFV-160, then that reviewer should also notify the TAD reviewers who are assigned the open M submissions of the final action. Ideally, reviewers should communicate with each other and their PM prior to the final action if the final P submission will be incomplete.

The PR for the Freedom of Information (FOI) Summary Q submission should notify the PM with an Appian notification when final action is taken.

IX. NON-ADMINISTRATIVE (180-DAY) APPLICATIONS

For a non-administrative original or supplemental application, the application PR requests a consult from each team responsible for am applicable TS, as well as other needed consults. Each CR determines the requirements for their TS and whether the information provided by the sponsor is sufficient to complete those requirements. For TSs previously deemed complete, each CR determines if any changes have occurred that would cause reevaluation of the TS and alerts the project team if the TS is no longer complete.

Within 30 days of receipt of the non-administrative application, if the application is 1) for use in a food-producing animal and 2) contains either an antimicrobial drug (regardless of medical importance)[9] or a drug intended as an alternative to traditional antimicrobials, the PR prepares the antimicrobial email alert using the ONADE Antimicrobial Alert email template and sends it to the OD and Deputy OD.[10] Typically, this means applications where safety and/or effectiveness was evaluated, but some major non-fee (NF) supplements may be of interest. This information does not need to be provided for non-fee labeling (NL) supplements, most NF labeling supplements, or CMC supplements. When in doubt, provide the requested information to the OD. After receipt of this information, the OD will determine whether to communicate further with others in CVM (e.g., the Center Director).

X. REFERENCES

CVM Program Policies and Procedure Manual – ONADE Reviewer's Chapter

1243.3026 – Assessing Submission Quality and Amending and Resetting the Clock on Submissions

[9] Except ionophores. It is not necessary to notify the ONADE Office Director prior to approval of ionophores.
[10] Also include the HFV-157 TL, the TAD reviewer's TL, the TAD reviewer's DD, and the project manage in the cc: line.

1243.3050 – Determining Technical Section Requirements for New Animal Drug Product Approval

1243.3060 – Implementing Shortened Review Times for New Animal Drug Application (NADA) Reactivations and Investigational New Animal Drug (INAD) File Resubmissions Using eSubmitter

1243.3200 – Routing a Request to Obtain a Consulting Review of a Submission Tracking and Reporting System (STARS) Submission

1243.3250 – Q-Submissions: Agency-Initiated Actions

1243.4080 – Labeling and All Other Information Technical Sections (Minor Technical Section or M Submissions)

1243.4085 – All Other Information

1243.5704 – Process for Eligible Sponsors to Obtain Conditional Approval

1243.5706 – Meeting to Discuss Post-Approval Responsibilities for Sponsors of Conditional Approvals

1243.5730 – Review of 60-day Original Animal Drug Availability Act of 1996 (ADAA) Feed Use Combination New Animal Drug Applications (NADAs)

1243.5761 – Freedom of Information (FOI) Summary for Original and Supplemental New Animal Drug Applications (NADA)

1243.5762 – Freedom of Information (FOI) Summary for an Animal Drug Availability Act (ADAA) Medicated Feed Combination New Animal Drug Application

ONADE Standard Operating Procedures

1243.100.004 – Process for Preparing Communications about New Animal Drug Approvals

1243.118.001 – Documenting and Confirming Test Article Information (Including Formulation) for Pivotal Data Submissions

1243.162.XXX DRAFT – Reopening the Environmental Impact Technical Section and Reevaluating Claims of Categorical Exclusion in the End Game

1243.166.001 – Clinical Pharmacology Team (HFV-166) Involvement and Communication During the Project Lifecycle

ONADE Office Policy Page

Initial Recommendations for the Addition of Approved by FDA Statements to Labeling

XI. VERSION HISTORY

June 9, 2011 – Original version

September 25, 2012 – Revised to incorporate references to the Fact Sheet

June 13, 2016 – Updated to current format and redacted internal information for public posting.

May 13, 2019 – Updated to specify how the project team confirms technical section status for a 180-day application, to reference the new SOP for updated categorical exclusion requests, and to remove references to the end-review amendment process.

January 27, 2020 – Updated to reflect changes to P&P 1243.4080 regarding M submissions STARS due dates and establishing new target due dates.

July 7, 2020 – Updated to include the PM responsibilities for sending consults and scheduling the end game meeting in Section III, confirming the drug formulation of the product used in TAS and Effectiveness studies are consistent with the product that will be approved in Section III, and the Day 150 Check-In process in Sections V and VI. Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

February 2, 2021 – Updated to point to Pre-CA Meeting P&P 1243.5706 Meeting to Discuss Sponsor Responsibilities following Conditional Approval

March 5, 2021 – Updated section V to reference the new ONADE SOP on preparing communications about new animal drug approvals (1243.100.004).

November 1, 2021 – Added reference to the new ONADE SOP for documenting and confirming test article information (1243.118.001).

March 22, 2022 - Updated to include more detail on scheduling the end game meeting, preparing, and taking final action on end game documentation, and where documentation is maintained. In addition, section III was updated to include 2 exceptions for supplemental approvals where there is no drug formulation information to verify. A new section V was created to document the project manager's process for preparing and taking final action on end game documentation.

July 18, 2022 – Quality systems review for minor formatting updates.

December 15, 2022 – Updates to align with updates to the ONADE policy document on approval of antimicrobials for food animals.

June 13, 2023 – Updates to add information related to the antimicrobial alert email (reference the ONADE template and remove references to the retired ONADE policy "Approval of Antimicrobials for Food Animals"). Information from the antimicrobial policy for food animals is being incorporated into our existing process documentation and the policy itself retired from the policy page in SharePoint. Updated to include more detail on who the PM sends meeting invites to, project and review team members. Added a note under the PM coordinating the end game that details the project team issuing Appian notifications to the PM when final action is taken. Updated the project team completes the Day 150 check-in to due date minus 30-day check-in and provided more detail on the responsibilities to occur. Added a new section for primary reviewer notifications when closing M submissions and the FOI Q. Added the Communication SOP into the references section.

August 8, 2023 – Updated to specify that when a PM checks on pending technical section submissions before starting the end game meeting procedure, if a technical section is

expected to go incomplete with SRT offered or if the reviewer is unsure, the PM will proceed with the end game meeting procedure. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

November 2, 2023 – Updated to fix minor formatting and grammar errors. Updated into the newly revised P&P template. Added to the August 8, 2023, version history that a font change was done at that time.

December 6, 2023 – Updated section VI. 4. The STARS Correction Request Form has been retired. The instructions are now that if another submission becomes the last P through a reset the clock action, to send an email to the EDSR Mailbox, requesting that the M submissions are linked to the correct P submission.