
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER’S CHAPTER

IMPLEMENTING SHORTENED REVIEW TIMES FOR ABBREVIATED NEW ANIMAL DRUG APPLICATIONS (ANADA) REACTIVATIONS AND GENERIC INVESTIGATIONAL NEW ANIMAL DRUG (JINAD) RESUBMISSIONS

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I. PURPOSE

This document describes the Office of New Animal Drug Evaluation’s (ONADE) procedures for implementing shortened review time (SRT) for reactivations of abbreviated new animal drug applications (ANADAs) and certain resubmissions to generic investigational new animal drug (JINAD) files.

II. BACKGROUND

On October 1, 2013, CVM implemented a process for SRT for reactivations and certain resubmissions as outlined in the Animal Generic Drug User Fee Act (AGDUFA) Reauthorization Performance Goals and Procedures – Fiscal Years 2014 through 2018 (AGDUFA II Goals Letter). Refer to Section IV of this document for the criteria to determine whether an application or submission may qualify for SRT when reactivated or resubmitted.

III. APPLICATION/SUBMISSION TYPES THAT MAY QUALIFY FOR SRT WHEN REACTIVATED OR RESUBMITTED

In the AGDUFA II Goals Letter, CVM identifies the ANADA and JINAD submissions that may qualify for SRT when they are reactivated or resubmitted. Table 1 summarizes each type and their associated review timeframes under the current reauthorization.

Table 1. CVM ONADE Review Times

Submission type: AGDUFA III Goals Letter terminology	Submission type: ONADE terminology	Initial submission: normal review time	Reactivation or resubmission: SRT
Non-administrative abbreviated new animal drug applications	Non-administrative original ANADA	240 days Submission code: A	120 days Submission code: E
JINAD study submission	Technical section (TS) submission	180 days Submission code: P	60 days Submission code: P

IV. CRITERIA FOR SHORTENED REACTIVATION OR RESUBMISSION REVIEW TIMES

CVM generally offers the shortened reactivation and resubmission times where possible. We expect sponsors to continue to submit high-quality submissions to facilitate review by ONADE.

If we decide to issue an application incomplete or TS incomplete letter, reviewers should confirm all of the following factors in their decision to offer SRT for a future ANADA reactivation or JINAD resubmission:

1. We can clearly identify and communicate to the sponsor the changes and/or submission of additional information that could reasonably be expected to complete the application or submission.
2. We can complete review of the ANADA reactivation or JINAD resubmission and make the review decision within the shortened review time.
3. All consulting reviews and the primary review, when taken as a whole, support the decision to offer SRT.

Based on these criteria, CVM states in the incomplete or non-concurrence letter whether the future ANADA reactivation or JINAD resubmission may qualify for SRT and indicates the appropriate review timeframe. The letter outlines the criteria to qualify for the SRT.

Because the decision to offer SRT is situation-dependent, the determination of whether to offer it when issuing an incomplete or non-concurrence letter involves the judgment of the primary reviewer (PR) in conjunction with the consulting reviewers (CRs). As necessary, the PR should keep the team leader (TL) and CRs informed to assure consistency across ONADE.

V. MEETINGS TO DISCUSS INCOMPLETE OR NON-CONCURRENCE LETTERS

If a sponsor wants to discuss proposals to address the deficiencies in the incomplete letter, they can do so informally or formally. Informal communication occurs by email or telephone and does not result in a memorandum of conference (MOC). If the sponsor wants a formal meeting with an MOC, the sponsor should submit a formal meeting request (submission type code Z) as described in P&P 1243.3024.

VI. EVALUATION OF THE REACTIVATION OR RESUBMISSION

Once received, examine the ANADA reactivation or JINAD resubmission to confirm it qualifies for SRT by meeting the criteria below.

1. The sponsor certifies (either in the cover letter or in eSubmitter) that no additional information beyond the scope of addressing the comments/deficiencies was included in the ANADA reactivation or JINAD resubmission.
2. CVM determines that the sponsor only included additional information that adequately addresses the comments and deficiencies stated in the initial incomplete or non-concurrence letter.

VII. HANDLING SUBMISSIONS THAT ARE DEFICIENT OR CONTAIN UNSOLICITED ADDITIONAL INFORMATION

CVM will utilize the procedures established for refuse to file (RTF) and refuse to review (RTR) as applicable and warranted, per P&P 1243.2050. CVM will continue to apply the minor amendment process as appropriate, per P&P 1243.3026. CVM will also utilize the change review time and reset the clock processes, as appropriate.

A. Utilizing the Change Review Time Process

If the sponsor includes unrequested information in the parent submission of the reactivation or resubmission, it may no longer qualify for SRT. If we determine that such a reactivation or resubmission does not qualify for SRT, we will change the review time to the normal review time using the change review time process in Appian and notify the sponsor (refer to Table 1 for normal review times).

B. Utilizing the Reset the Clock Process

When we request an amendment during the SRT process, we have determined we need information and if the sponsor can submit the information in the agreed timeframe, we can complete our review in the SRT established timeframe. It is important to note that if we receive an unsolicited amendment or an amendment that contains unrequested information during the SRT without a sponsor having a prior conversation with us, we will utilize the 'reset the clock' process on that reactivation or resubmission if the review team determines the information is not minor in nature and there isn't sufficient time to complete the review of the submission within the SRT. When we reset the clock on a reactivation or resubmission, we base its new due date upon the received date of the amendment, set the review timeframe to the normal review time associated with the submission type, and notify the sponsor (see P&P 1243.3026).

C. Utilizing Another SRT

If, after review of the submitted information, we find that a reactivation or resubmission is still incomplete, we will issue another incomplete or non-concurrence letter to the sponsor. Using the same criteria above, we will determine if we can offer another shortened reactivation or resubmission review time in the next review cycle. There is no limit on the number of review cycles a reactivation or resubmission may qualify for SRT. If we determine that a reactivation or resubmission does not qualify

for SRT in the next review cycle, it is assigned the normal review time (refer to Table 1 for the normal review times).

VIII. ACTIONS ON ANADA/JINAD SUBMISSIONS AND REACTIVATIONS/RESUBMISSIONS

The following tables summarize the Appian actions available to reviewers and include the new Final Action Codes for offering SRT. The actions apply to non-administrative original ANADA and JINAD TS submissions. The available actions in the tables below also apply to ANADA reactivations and JINAD resubmissions.

Table 2. Appian Actions for Non-administrative ANADA Applications (submission type code C, A, R, E)

Appian Action	Description
RTF	Refer to P&P 1243.2050
Withdraw of pending supplement	If the sponsor submits an amendment requesting to withdraw the pending supplement, we discontinue the review of the application and issue an acknowledgement letter.
Application complete (approvable)	If we consider the application complete based on the submitted information, we issue the appropriate approval letter.
Application incomplete	If we consider the application incomplete based on the submitted information and SRT upon reactivation is not possible, we issue an incomplete application letter.
Application incomplete shortened review reactivation offered	If we consider the application incomplete based on the submitted information but SRT upon reactivation is possible, we will issue an incomplete application, SRT offered letter. FINAL ACTION CODE: (INC APP SR) INCOMPLETE APPLICATION; SHORTENED REVIEW REACTIVATION OFFERED; LETTER SENT

Table 3. Appian Actions for JINAD TS Submissions (submission type code P)

Appian Action	Description
Refuse to Review	If we consider the submission wholly incomplete on its face, we issue a RTR letter within 60 days of receipt.
Stop Review	If the sponsor submits an amendment requesting we stop review, we discontinue review of the submission and issue an acknowledgement letter.
Technical Section Complete	If we consider the submission acceptable and it completes a TS based on the submitted information, we issue a TS complete letter.
Submitted Information Acceptable, Technical Section Incomplete	If we consider the submitted information acceptable but other aspects of the TS remain incomplete, we issue a submitted information acceptable, TS incomplete letter.
Technical Section Incomplete; Submitted Information not Acceptable	If we consider any of the submitted information unacceptable, the TS is incomplete, and we do not offer shortened resubmission review. We issue a TS incomplete letter.
Technical Section Incomplete, Shortened Review Resubmission Offered	If we consider the TS incomplete based on the submitted information but SRT upon resubmission is possible, we issue a TS incomplete, SRT offered letter. FINAL ACTION CODE: (TS INC SR) TECHNICAL SECTION INCOMPLETE; SUBMITTED INFORMATION NOT ACCEPTABLE; SHORTENED REVIEW RESUBMISSION OFFERED; LETTER SENT

A. Initial Submission – Normal Review Time

When a sponsor submits the initial submission, STARS assigns the normal review timeframe to the submission. CVM's Electronic Submission System (ESS) generates a submission receipt advising the sponsor of the CVM due date. This receipt is sent via the Electronic Submissions Gateway (ESG).

The PR follows conventional CVM review procedures to review and close out the submission in Appian within the normal review timeframe (see Table 1). Refer to Tables 2 and 3 for the available actions.

B. Reactivation or Resubmission

If CVM offered a shortened reactivation or resubmission review time in the incomplete letter, reviewers follow the process outlined in #1 below. If CVM did not offer shortened reactivation or resubmission review time in their incomplete letter, reviewers follow the process outlined in #2 below.

1. CVM offered the sponsor SRT for their reactivation or resubmission in the incomplete letter to the initial submission.

When the sponsor submits the reactivation or resubmission, STARS assigns the SRT. If the reactivation or resubmission was submitted in eSubmitter, the sponsor receives a submission receipt via the ESG advising them of the CVM due date. If CVM determines at any point during the review, using the criteria in Section IV, that the submission does not meet the criteria for SRT, we will change the review time to the normal review timeframe (see Table 1).

The PR follows the instructions in the Appian User Guide to change the review timeframe using the 'Review Time Change' Appian Workflow. Before changing the review time, the PR prepares the notification letter template (located in the ONADE Templates SharePoint) to be sent to the sponsor advising them of the new CVM due date. The PR uploads the Review Time Change letter in Appian during the Review Time Change Appian Workflow.

The PR follows conventional CVM review procedures to review and closes out the submission in Appian either within the SRT or normal review time.

2. CVM did not offer the sponsor SRT in their incomplete letter.

When a sponsor submits the reactivation or resubmission, STARS assigns the normal review timeframe to the submission. The sponsor receives a submission receipt via the ESG advising them of the CVM due date.

The PR follows conventional CVM review procedures to review and closes out the submission in Appian within the normal review timeframe (see Table 1). Refer to Table 2 and 3 for the available final actions.

C. JINAD Phased Review Process – Impact of Last Pending Technical Section Submission (Submission Type Code P)

During the end game, the 'last TS submission' (frequently referred to as the last P) under review is the TS submission with the latest CVM due date and the last TS can have a 180-day, or 60-day review time (see P&P 1243.3051 for details on the end game). The most recently submitted TS may not be necessarily the last P.

1. Initial Submission - Normal 180-day review time

The due date for the Labeling TS (submission type code M; described in P&P 1243.4080) assumes the due date of the last pending TS submission (submission type code P). The sponsor should submit the Labeling TS no later than 80 days into the review of the last TS. The review time for the Labeling TS is usually around 100 days, but it can be longer or shorter depending on when the sponsor submits the Labeling TS. If the sponsor is late in submitting the Labeling TS, the PR and TL assign an appropriate due date that may not be reflected in STARS but is communicated to the sponsor.

If we incomplete one or more of the pending P submissions, we continue a thorough review of the Labeling TS commensurate with the information available at that time and include our review findings in the Labeling TS incomplete letter.

EXAMPLE: The Chemistry, Manufacturing, and Controls (CMC) technical section is the last pending technical section submission. The M submission is submitted and given the same due date as the CMC P submission. All other technical sections are complete. The Division of Manufacturing Technologies notifies the target animal reviewer that it will incomplete the submission. The target animal reviewer continues the review of the Labeling technical section, allowing time for the primary and consulting reviews (such as the Office of Surveillance and Compliance). The target animal reviewer will include CVM's comments in the Labeling technical section incomplete letter. The target animal reviewer should indicate in the Labeling incomplete letter that CVM might make additional changes to the labeling when the labeling is reviewed as a whole. The sponsor should incorporate our comments before resubmitting the Labeling technical sections in the next review cycle.

2. Resubmission - Shortened 60-day review time (Last P)

The due date for the Labeling TS assumes the due date of the last pending TS submission (submission type code P). If the sponsor submits the Labeling TS late, the PR and TL assign an appropriate due date that may not be reflected in STARS but is communicated to the sponsor. The PR and TL look at the pending P submissions and ensure that any pending M submission references the 'last P' submission.

IX. REFERENCES

AGUFA III Goals Letter:

<https://www.fda.gov/media/116328/download>

Appian User Guide:

Internal information redacted.

CVM Policies and Procedures (P&P) Manual – ONADE Reviewer's Chapter

1243.2050 - Refuse to File and Refuse to Review

1234.3024 - Scheduling and Holding Meetings with Outside Parties

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

1243.3051 - Verifying Scope and Technical Status for Phased Review Investigational New Animal Drug (INAD) Projects in the End Game

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

ONADE Templates

Review Time Change Letter

X. VERSION HISTORY

October 1, 2014 – Original version.

March 15, 2017 – Reformatted to current format for P&Ps and corrected broken link to ONADE Template page in SharePoint

March 07, 2019 – Updated to include language about shortened review timeframe certifications that will be included in cover letters and eSubmitter, referenced end game information. Information on the Appian workflow was removed from the body of the P&P and the Appian User Guide included in the references. Minor edits and corrections were made through out for clarity.

July 16, 2019 – Updated FDA.gov URL links to new directed links due to migration of new FDA.gov Website. No other updates needed.

July 1, 2020 - Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

September 23, 2020 – Created a new section on handling submissions that are deficient or contain unsolicited information. Clarified information on resetting the clock and changing the review time to distinguish that the two are different and are utilized in different circumstances with different impacts on review due dates.

January 28, 2022 – Minor edit to the review times in Table 1 to align with the updated timelines under AGDUFA III.

March 24, 2022 - Revised table 2 to include Appian action of withdraw of supplement. Revised table 3 to include stop review and add information to the Appian action for Technical Section Incomplete. Technical Section Incomplete now includes “Submitted Information not Acceptable”. Revised the description to state if any of the submitted information in the technical section is unacceptable, the technical section is incomplete. Revised reference section.

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

March 28, 2024 – Revised section VIII. to remove mention of protocols, because shortened review timeframes for generic new animal drugs apply only to reactivations of non-administrative applications (ANADA E submissions) and technical section submissions (JINAD P submissions) under the JINAD. In addition, the font of this document was changed from Verdana 10-point font to Arial 11-point font. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. This document was put into the current office format.