
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) RESUBMISSION

I.	Purpose	1
II.	Background.....	1
III.	Types of applications/submissions that may qualify for shortened reactivation or resubmission review times	1
IV.	Criteria for shortened reactivation review times	2
V.	Actions on ANAD/JINAD submissions and reactivations/resubmissions	4
VI.	References	8
VII.	Version history	9

I. PURPOSE

The purpose of this document is to describe the Office of New Animal Drug Evaluation's (ONADE) procedures for implementing shortened review times for reactivations of abbreviated new animal drug applications (ANADA) and certain resubmissions to the generic investigational new animal drug (JINAD) file.

II. BACKGROUND

On October 1, 2013, the Center for Veterinary Medicine (CVM) implemented a process for shortened review times 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).¹ Refer to Section IV of this document for the criteria to determine whether an application or submission may qualify for shortened reactivation or resubmission review timeframe.

III. TYPES OF APPLICATIONS/SUBMISSIONS THAT MAY QUALIFY FOR SHORTENED REACTIVATION OR RESUBMISSION REVIEW TIMES

In the AGDUFA II Goals Letter, CVM identifies the ANADA and JINAD submissions that may qualify for shortened review timeframes when they are reactivated or resubmitted. Table 1 summarizes these submission types and their associated review timeframes.

¹ AGDUFA II Goals Letter
<https://www.fda.gov/media/85746/download>

Table 1. CVM ONADE Review Times

Submission Type: ADUFA III Goals Letter Terminology	Submission Type: CVM ONADE Terminology	Initial Submission: Normal Review Time	Reactivation or Resubmission: Shortened Review Time
Non-administrative abbreviated new animal drug applications	Non-administrative original ANADA	270 days Submission code: A	190 days Submission code: E
JINAD study submission	Technical section submission	270 days Submission code: P	90 days Submission code: P

IV. CRITERIA FOR SHORENED REACTIVAITON REVIEW TIMES

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

CVM will utilize the procedures established for refuse to file (RTF) and refuse to review (RTR) as applicable and warranted.² CVM will continue to apply the minor amendment process as appropriate.³

If we decide to issue an application incomplete or technical section incomplete letter, reviewers should confirm all of the following factors in their decision to offer a shortened review timeframe 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 shortened review time.

Based on the criteria above, CVM will state in the incomplete or non-concurrence letter whether the future ANADA reactivation or JINAD resubmission may qualify for a shortened review time and indicate the appropriate review timeframe. The letter will outline the criteria to qualify for the shortened review time.

² P&P 1243.2050 Refuse to File and Refuse to Review

³ See P&P 1243.3026 Amending and Resetting the Clock on Stars Submissions

Because the decision to offer shortened review time will be situation-dependent, the determination of whether to offer it when issuing an incomplete or non-concurrence letter involves the judgment of the primary reviewer in conjunction with the consulting reviewers. As necessary, the primary reviewer should keep the team leader and consulting reviewers informed to assure consistency across ONADE.

If a sponsor wants to discuss proposals to address the deficiencies in the incomplete letter, they can do so informally or formally. Informal communication can occur 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).⁴

Once received, an ANADA reactivation or JINAD resubmission qualifies for shortened review timeframe if:

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.

If the sponsor submits unrequested information, the reactivation or resubmission may not qualify for shortened review time. When we determine that a reactivation or resubmission does not qualify for shortened review time, we will change the review time to the normal review time⁵ and notify the sponsor.⁶

If, after review of the submitted information, we find that a reactivation or resubmission is still incomplete, we issue another incomplete or non-concurrence letter to the sponsor.

Using the same criteria above, we 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 shortened review time.

If we determine that a reactivation or resubmission does not qualify for shortened review time in the next review cycle, it will be assigned the normal review time (refer to Table 1 for the normal review times).

⁴ P&P 1243.3024 Scheduling and Holding Meetings with Outside Parties

⁵ Appian User Guide
Internal information redacted

⁶ Refer to Table 1 in this P&P for normal review times.

V. ACTIONS ON ANAD/JINAD SUBMISSIONS AND REACTIVATIONS/RESUBMISSIONS

The following tables summarize the Appian actions available to reviewers and include the new Final Action Codes for offering shortened review. The actions apply to non-administrative original ANADA and JINAD technical section submissions and protocols. 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
Refuse to file	Refer to P&P 1243.2050 Refuse to File and Refuse to Review
Application Complete (Approvable)	If we consider the application complete based on the submitted information, we will issue the appropriate approval letter.
Application Incomplete	If we consider the application incomplete based on the submitted information and shortened review upon reactivation is not possible, we will issue an incomplete application letter.
Application Incomplete Shortened Review Reactivation Offered	If we consider the application incomplete based on the submitted information but a shortened review upon reactivation is possible, we will issue an incomplete application, shortened review offered letter. FINAL ACTION CODE: (INC APP SR) INCOMPLETE APPLICATION; SHORTENED REVIEW REACTIVATION OFFERED; LETTER SENT

Table 3. Appian Actions for JINAD Technical Section Submissions (Submission type code P)

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

A. Initial Submission – Normal Review Time

When a sponsor submits the initial submission, STARS will assign the normal review timeframe to the submission. will generate a submission receipt advising the sponsor of the CVM due date. This receipt will be sent via the Electronic Submissions Gateway (ESG).

The primary reviewer will follow conventional CVM review procedures to review and close out the submission in Appian within the normal review timeframe.⁷ 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 their incomplete letter, reviewers should follow the process outlined in #1 below. If CVM did not offer shortened reactivation or resubmission review time in their incomplete letter, reviewers should follow the process outlined in #2 below.

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

When the sponsor submits the reactivation or resubmission, STARS will assign the shortened review time. If the reactivation or resubmission was submitted using eSubmitter, the sponsor will receive 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 of this P&P, that the submission does not meet the criteria for shortened review time, we will change the review time to the normal review timeframe.⁸

The primary reviewer should follow the instructions in the Appian User Guide to change the review timeframe using the Review Time Change Appian Workflow.⁹ Before changing the review time, the primary reviewer prepares the notification letter to be sent to the sponsor advising them of the new CVM due date.¹⁰ The primary reviewer will upload the Review Time Change letter in Appian during the Review Time Change Appian Workflow.

The primary reviewer will follow conventional CVM review procedures to review and close out the submission in Appian either within the shortened review time or normal review time.

⁷ Refer to Table 1 in this P&P for review timeframes.

⁸ Refer to Table 1 in this P&P for review timeframes.

⁹ Appian User Guide:
Internal information redacted

¹⁰ Review Time Change Letter template is located on the ONADE Template SharePoint site:
Internal information redacted

2. CVM did not offer the sponsor shortened review time in their incomplete letter.

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

The primary reviewer will follow conventional CVM review procedures to review and close out the submission in Appian within the normal review timeframe.¹¹ Refer to Table 2 and 3 for the available final actions.

C. Reset the Clock on a Reactivation or resubmission

If we receive an amendment with new or unrequested information during a shortened review timeframe, we may reset the clock on that reactivation or resubmission.¹² CVM will base the new due date for the reactivation or resubmission upon the receipt date of the amendment. After we reset the clock, we will review the reactivation or resubmission in the normal review timeframe (refer to Table 1 for review times).

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

During the end game¹³, the 'last technical section submission' (frequently referred to as the last P) under review is the technical section submission with the latest CVM due date and the last technical section can have a 270-day, 100-day, or 90-day review time. The most recently submitted technical section may not be necessarily the last P.

1. Initial Submission - Normal 270-day review time

The due dates for the Labeling technical section submission (submission type code M)¹⁴ assume the due date of the last pending technical section submission (submission type code P). The sponsor should submit the Labeling technical sections no later than 80 days into the review of the last technical section. The review time for the Labeling technical sections is usually around 100 days, but it can be longer or shorter depending on when the sponsor submits the Labeling section. If the sponsor is late in submitting the Labeling technical section, the primary reviewer and team leader will 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 will continue a thorough review of the Labeling technical section commensurate

with the information available at that time and include our review findings in the Labeling technical section incomplete letter.

¹¹ Refer to Table 1 in this P&P for review timeframes.

¹² See P&P 1243.3026 Amending and Resetting the Clock on STARS Submissions

¹³ See P&P 1243.3051 Verifying Scope and Technical Section Status for Phased Review in the End Game

¹⁴ See P&P 1243.4080 Labeling and All Other Information Technical Sections (Minor Technical Section)

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 letters. 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 technical section submission assumes the due date of the last pending technical section submission (submission type code P). If the sponsor submits the Labeling technical sections late, the primary reviewer and team leader will assign an appropriate due date that may not be reflected in STARS but is communicated to the sponsor. The primary reviewer and team leader will look at the pending P submissions and ensure that any pending M submission references the 'last P' submission.

VI. REFERENCES

AGUFA II Goals Letter:

<https://www.fda.gov/media/85746/download>

Appian User Guide: Internal information redacted

CVM Program Policies and Procedure Manual

1243.2050 Refuse to File and Refuse to Review

1234.3024 Scheduling and Holding Meetings with Outside Parties

1243.3026 Amending and Resetting the Clock on STARS Submissions

1243.3051 Verifying Scope and Technical Status for Phased Review ([J]INAD) in the End Game

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

VII. 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.