
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

VOIDING SUBMISSIONS AND DISCONTINUING THE REVIEW OF PENDING SUBMISSIONS AND APPLICATIONS

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I. PURPOSE

This document explains how to process submissions or applications that should no longer be considered for review. This includes submissions that the sponsor inadvertently submitted (e.g., duplicate submission or information submitted to the wrong file) and submissions that the sponsor no longer wants reviewed.

When a sponsor requests that a submission or application no longer be considered for review, it is important to first determine the reason for stopping the review and then decide the best course of action; voiding the submission, stopping review of the submission, or withdrawing the pending application. The Office of Surveillance and Compliance processes the withdrawal of approved applications, and so those withdrawals will not be addressed in this document.

For submissions and applications that CVM determines are unacceptable for review or unacceptable for filing, respectively, see P&P 1243.2050.

II. VOIDING SUBMISSIONS

A submission may be voided when it is determined that the sponsor submitted it in error. Examples include a sponsor submitting duplicate submissions, or the sponsor submitted information to the wrong administrative file or application. Regardless of whether we or the sponsor realizes the error, it is important to communicate our intention to void the submission with the sponsor via phone or email.

We may void any Submission Tracking and Reporting System (STARS) submission or amendment submitted either in paper or via eSubmitter using the ONADE Void Submission workflow under the Actions tab in Appian. You will need to ensure that all consults are returned, if applicable, prior to starting the Void Submission workflow. Teamleader concurrence in Appian is required for all Void Submission actions. At the conclusion of the workflow, all information that the sponsor submitted will be deleted, and it will not be possible to recover this information. Only the STARS metadata for the submission is retained (e.g., submission number, purpose of submission, review summary, etc.). No review documentation or letters are generated. Therefore, it is important to document the reason the submission was voided in the Review Summary field, as this will be the only record of our decision. The ONADE Void Submission workflow will collect the Review Summary information for all voided parent

submissions. However, the ONADE Void Submission workflow will not collect the Review Summary information when only an amendment is voided. When voiding only an amendment, you will need to document the reason for the void in the Review Summary field of the parent submission.

There are time constraints for voiding submissions. Submissions to investigational new animal drug (INAD) files and generic investigational new animal drug (JINAD) files must be voided within 60 days of receipt, and submissions to new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) must be voided within 30 days of receipt. If the submission is past these timeframes, the only available action is for the sponsor to request that we Stop Review of the submission or withdraw the pending application. There are no time limits for voiding submissions to all other administrative file types (e.g., general correspondence files (GC), veterinary master files (VMF), etc.).

III. STOP REVIEW

Use the Stop Review process when a sponsor requests that we no longer consider the submitted information for review. This process is appropriate for submissions to (J)INAD, VMF, and GC files. In these situations, the sponsor must submit an amendment requesting that we Stop Review. You will need to either draft a brief submission summary stating that the review of the submission was stopped per the sponsor's request or make a similar note in the Review Summary field, and draft an acknowledgement letter. An acknowledgement letter will always be sent for a Stop Review. You should reference the amendment in which the sponsor made the request to stop review in your submission summary/Review Summary field and letter. When completing the final action package for the submission in Appian, use the final action code: STOP REV - SUBMISSION REVIEW TERMINATED AT SPONSOR REQUEST; LETTER SENT.

IV. WITHDRAWAL OF A PENDING APPLICATION OR SUPPLEMENT

Sponsors may request the withdrawal of a pending original or supplemental (A)NADA. This process is similar to the Stop Review process above but is appropriate for applications instead of (J)INAD, VMF, and GC files. The sponsor must submit an amendment requesting the withdrawal of the pending application. You will need to either draft a brief submission summary stating that per the sponsor's request, the pending application or supplemental application was withdrawn or make a similar note in the Review Summary field, and draft an acknowledgement letter. An acknowledgement letter will always be sent for a Withdrawal. You should reference the amendment in which the sponsor made the request to withdraw the application in your submission summary/Review Summary field and letter. When completing the final action package for the submission in Appian, use the final action code WDPAPP SP - PENDING APPLICATION WITHDRAWN BY REQUEST OF SPONSOR; LETTER SENT for original applications or reactivations and WDPSUP SP - PENDING SUPPLEMENT WITHDRAWN BY REQUEST OF SPONSOR; LETTER SENT for supplements and reactivations.

V. REFERENCES

CVM Program Policies and Procedure Manual

1243.2050 – Refuse to File and Refuse to Review

VI. VERSION HISTORY

March 12, 2018 – Original version.

December 18, 2018 – Revised section II to no longer require the project managers to be the ones communicating with the sponsors about voided submissions. It is more efficient to have the primary reviewer do that.

October 19, 2020 - Updated to clarify how to document when a sponsor requests we stop review of a submission and documentation that is required.