VOIDING SUBMISSIONS AND DISCONTINUING THE REVIEW OF PENDING SUBMISSIONS AND APPLICATIONS

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 submissions, 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 submitting 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 Premarket Void Submission workflow under the Actions tab in Appian. Ensure that all consults are returned, if applicable, prior to starting the Void Submission workflow. Branch Chief concurrence in Appian is required for all Void Submission actions. At the conclusion of the workflow, all information that the sponsor submitted is 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 Premarket Void Submission workflow collects the Review Summary information for all voided parent submissions. However, the Premarket Void Submission workflow does not collect the Review Summary information when only an

amendment is voided. When voiding only an amendment, document the reason for the void in the Review Summary field of the parent submission.

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

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. 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. Draft an acknowledgement letter since an acknowledgement letter is always sent for a Stop Review. In the submission summary/Review Summary field and letter, reference the amendment in which the sponsor made the request to stop review. 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. Draft either 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. Draft an acknowledgement letter since an acknowledgement letter us always sent for a Withdrawal. Reference the amendment in which the sponsor made the request to withdraw the application in the submission summary/Review Summary field and letter. When completing the final action package for the submission in Appian, use the final action code WD PAPP SP - PENDING APPLICATION WITHDRAWN BY REQUEST OF SPONSOR; LETTER SENT for original applications or reactivations and WD PSUP SP - PENDING SUPPLEMENT WITHDRAWN BY REQUEST OF SPONSOR; LETTER SENT for supplements and reactivations.

V. WITHDRAWAL OF A CLOSED-OUT MANUFACTURING SUPPLEMENT

For CMC supplemental (A)NADAs, sponsors may request withdrawal of a closed-out submission. This may be done in two ways. If the supplement was found incomplete, the sponsor may either reactivate to withdraw or use the G submission approach below. If the supplement was approved, the sponsor will use the G submission approach below.

A. Supplement reactivation with a withdrawal request

The sponsor may submit a reactivation that requests withdrawal of the supplement. Include a note in the Review Summary field stating that, per the sponsor's request,

the pending supplemental application was withdrawn. When completing the final action package for the submission in Appian, use the final action code WD PSUP SP - PENDING SUPPLEMENT WITHDRAWN BY REQUEST OF SPONSOR; LETTER SENT.

B. G submission withdrawal request

The sponsor may submit a General Correspondence (G) submission to the affected (A)NADA files requesting withdrawal of the closed-out supplement(s). Draft an acknowledgement letter and reference in the Review Summary field and letter the applicable closed-out supplement number(s) that the sponsor requests to withdraw. When completing the final action package for the submission in Appian, use the final action code ACK.

VI. REFERENCES

CVM Policies and Procedures Manual – ONAPE and OGAD Reviewer's Chapter

1243.2050 – Refuse to File and Refuse to Review

Appian User Guide

Internal information redacted.

VII. 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.

July 21, 2022 - Quality systems review for minor formatting updates. The use of the word "you" was removed and the sentences reworded throughout the document

September 25, 2024 – 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. The document was put in the current format and minor punctuation errors were fixed. Brackets were changed to parenthesis in section II.

July 30, 2025 – Minor editorial updates. Added the section "Withdrawal Of A Closed-Out Manufacturing Supplement" to clarify how withdrawn manufacturing supplements are handled in the Divisions of Manufacturing Technologies. Updated to add Office of Generic Animal Drugs (OGAD) to the header and footer.