VERIFYING SCOPE AND TECHNICAL SECTION STATUS FOR PHASED REVIEW INVESTIGATIONAL NEW ANIMAL DRUG (INAD) PROJECTS IN THE END GAME

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I. PURPOSE

The purpose of this document is to explain how the Office of New Animal Drug Evaluation (ONADE) verifies the scope and technical section status for phased review projects in the end game.

This document applies to:

- All investigational new animal drug (INAD) or new animal drug application (NADA) projects that will culminate in original approvals, including Animal Drug Availability Act of 1996 (ADAA) combinations,[1] and
- INAD, NADA, or abbreviated new animal drug application (ANADA) projects that will culminate in supplemental approvals that require safety and/or effectiveness data (including bioequivalence).[2]

II. BACKGROUND

A phased review project is considered to be in the "end game" when the last P submission is received by ONADE. It is at this point the project team meets to verify that the project scope is the same for all applicable major technical sections, and to confirm the status of all applicable major technical sections.[3] The project team consists of the project manager (PM) and at least one representative from each team involved in the review of each applicable major technical section. Technical section status may be "complete" or "pending." The project team may also use the meeting to discuss any issues with the project and/or preparations for the approval.

III. PROJECT TEAM MEETS UNDER A Q SUBMISSION

When ONADE receives the last P submission for a phased review project, the assigned project manager (PM) will create a Q submission, assign it to themselves and send

[1] For 60-day ADAA procedures, refer to 1243.5730 Review of 60-day Original Animal Drug Availability Act of 1996 (ADAA) Feed Use Combination New Animal Drug Applications

[2] Category II supplements as described in 21 CFR 514.106(b)(2)

[3] An applicable technical section is a technical section required for that type of project. For example, Human Food Safety is not an applicable technical section for a companion animal project.

requests for consulting reviews to the reviewers or teams responsible for the applicable major technical sections. Once the consults have been assigned, the PM will schedule a meeting with the consulting reviewers and their team leaders, no later than approximately 90 days into the review of the last 180-day P submission.

The purpose of the meeting is to verify that the project scope is the same for all applicable technical sections, confirm the status of all applicable technical sections, and discuss any issues with the project.

During the meeting, the PM will ask the consulting reviewers to:

- Verify whether the project scope is the same for each technical section. Consulting reviewers will determine whether any changes have occurred in the project that would cause reevaluation of any technical section requirements.
- Confirm the status of each technical section. Consulting reviewers may identify technical section status as "complete" or "pending (i.e., under review)".
    - For technical sections that are complete, confirm whether the completed technical section is still valid. If a technical section is no longer considered complete letter, the consulting reviewers will determine what the sponsor needs to do to satisfy the technical section requirements, work with the PM to schedule an informal call with the sponsor to discuss this, and issue a formal letter to the sponsor notifying them that the technical section is no longer complete.[4]
- Identify any issues that could affect the approval. If issues are identified, the PM and consulting reviewers will work proactively with the sponsor to resolve them as efficiently as possible.

The PM will document the end game meeting using the ONADE "End Game Q" template and obtain concurrence from all consulting reviewers. If the drug is a new antimicrobial drug product for use in a food-producing animal, the PM will take the appropriate actions as outlined in the office policy "Approval of Antimicrobials for Food Animals" and document these in the end game memo.

IV. PROJECT MANAGER COORDINATES THE END GAME

The PM will perform the following activities as part of managing the project during the end game stage:

- Contact the sponsor if they have not submitted the All Other Information (AOI) and Labeling technical sections (M submissions) to coordinate the timing of the submissions. Ideally the sponsor will submit these no later than 80 days after submission of the last P submission.

[4] Internal information redacted.

- When the M submissions arrive, create the Freedom of Information (FOI) Q submission and assign it to the appropriate target animal division (TAD) team.
- Ensure that the M submissions reference the last P submission in the Submission Tracking and Reporting System (STARS) database. If the due date for the last P submission changes, confirm that the due dates for the M submissions change as well, and update the due date for the FOI Q submission. If a different P submission becomes the last P submission, submit a STARS Correction Request Form to request the M submissions reference the new last P submission, and update the due date for the FOI Q submission.
- If any of the technical sections are incompleted, notify the project team through email that the project has left the end game. When the technical section(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 (for example, 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).
- If a technical section is incompleted and shortened review time is offered, and the P submission with shortened review timeframe will be the last P submission, remind the sponsor to resubmit the M submissions at the same time as the technical section resubmission.
- When a technical section is resubmitted that qualifies for shortened review timeframe, 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.
- When the M submissions are resubmitted, create the FOI Q submission and assign it to the TAD team.
- 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.

V. NON-ADMINISTRATIVE (180-DAY) APPLICATIONS

For a non-administrative original or supplemental application, the primary reviewer of the application will send a request for consulting review to each of the divisions responsible for applicable technical sections, as well as other consultants needed for the review. Each consulting reviewer will determine the requirements for their technical section and whether the information provided by the sponsor is sufficient to complete those requirements. For technical sections previously deemed complete, each consulting reviewer will determine if any changes have occurred that would cause reevaluation of the technical section and alert the project team if the technical section is no longer complete.

VI. REFERENCES

CVM Program Policies and Procedure Manual

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

1243.3060 – Implementing Shortened Review Times for NADA Reactivations and INAD Resubmissions Using eSubmitter

1243.3250 - Q-Submissions Agency-Initiated Actions

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

Internal information redacted.

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VII. 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.