DETERMINING TECHNICAL SECTION REQUIREMENTS FOR A NEW ANIMAL DRUG PRODUCT APPROVAL

I. PURPOSE

The purpose of this document is to explain:

- why the Center for Veterinary Medicine (CVM) encourages sponsors to confirm technical section requirements either by requesting a presubmission conference (PSC) or submitting an investigational new animal drug (INAD) C[1] submission for written feedback on the proposed development plan (herein referred to as a C submission);
- timing considerations for confirmation of the technical section requirements; and
- what CVM will do if sponsors do not confirm some or all technical section requirements or a change in the scope of the project after a PSC or INAD C submission.

This document applies to:

- all INAD or new animal drug application (NADA) projects that will culminate in original approvals, including Animal Drug Availability Act of 1996 (ADAA) combinations, and
- INAD, NADA, or abbreviated new animal drug (ANADA) projects that will culminate in Category II (A/N-C-B1) supplemental approvals.

This document does not apply to Category I supplemental approvals (labeling supplements or Chemistry, Manufacturing, and Controls (CMC) supplements).[2]

[1] Submissions to request written feedback on a product development plan were previously classified under the H submission code (ONADE pilot project from March 15, 2021, through September 29, 2023).
[2] Category I supplements as described in 21 CFR 514.106(b)(1).

II. THE IMPORTANCE OF CONFIRMING TECHNICAL SECTION REQUIREMENTS PRIOR TO APPLICATION FOR APPROVAL

For each new project defined above in the Purpose section, the assigned project manager (PM) will encourage the sponsor to either request a PSC or submit a C submission for written feedback to determine the requirements for each applicable technical section for the project.[3] The Office of New Animal Drug Evaluation (ONADE) tasked the PM teams with this responsibility for several reasons:

- PSCs are an opportunity for CVM and the sponsor to reach agreement on the overall regulatory pathway,
- PSCs provide a forum for CVM and the sponsor to confirm any interdependencies that may exist between technical sections,
- PSCs and C submissions allow CVM and the sponsor to create shared expectations, ideally early in development, regarding data or information required to support approval, and
- PSCs and C submissions create shared expectations on the entirety of the development plan to ensure approval of the product is not delayed.

In processing the PSC request[4] or C submission[5], the PM:

- identifies the review team; in addition to the PM, the review team consists of at least one representative from each team involved in the review of each applicable major technical section,
- notifies the review team of the project initiation through consult requests, and
- works with the review team to determine the technical section requirements for approval.

The review team determines technical section requirements based on the project scope as provided by the sponsor. The project scope includes information relevant to the application, such as: established name, dosage form, dose, duration, route of administration, species and class, and indication. Determining technical section requirements means that the project team will determine for each applicable technical section whether:

- no new submission is required (e.g., the technical section is not affected by a supplemental change, or the sponsor is able to reference a completed technical section from another application),
- new submission(s) are required to complete the technical section, or
- CVM is unable to make a determination, because the sponsor needs to better define the scope of the project.

[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.
[4] See 1243.3024 Scheduling and Holding Meetings with Outside Parties.
[5] See 1243.4090 Processing a Sponsor Request (C Submission) for Written Feedback Regarding Development Plans for New Animal Drug Product Approvals

III. TIMING CONSIDERATIONS FOR CONFIRMATION OF TECHNICAL SECTION REQUIREMENTS

A. Presubmission Conference (PSC) Requests

The first PSC for the project will normally be the meeting in which CVM and the sponsor determine technical section requirements. When a sponsor identifies in eSubmitter that a meeting is the first PSC, the template unlocks questions allowing the sponsor to share their development plan and request input across all applicable technical sections without requiring all representatives to be present for discussion in the meeting. PMs will encourage sponsors to take advantage of this option.

For some projects, the sponsor may identify a narrow aspect of a technical section (e.g., carcinogenicity concerns or anticipated withdrawal time) as "make-or-break" for the project and desire a first PSC focused solely on that specific aspect. In these cases, the PM and sponsor, in coordination with the PM's team leader, may agree that a PSC to discuss the development plan across all technical sections will be held after the sponsor has confirmed the conclusion for their "make-or-break" issue. In these cases, the PM will work with the sponsor on how to submit their various PSC requests in eSubmitter.

B. C Submission Requests for Written Feedback

For some projects, the sponsor may decide to proceed through development without requesting a PSC:

- ONADE's preferred approach for establishing shared expectations with the sponsor is for the sponsor to request a PSC to discuss their development plan across all applicable technical sections. This is to ensure approval of the product is not delayed. For new original NADAs, the PM will continue to encourage the sponsor to request a PSC as stated above.

- for projects that will culminate in a B1 supplemental approval to an approved NADA, the PM will encourage the sponsor to submit their proposed development plan in a C submission for written feedback. However, after review of the C submission, should CVM have any concerns depending on the nature of the proposed plan, CVM may recommend a PSC meeting to be held.

Sponsors may use the C submission to request written feedback on development plans when seeking feedback on:

- proposed development plans for B1 supplemental approvals (e.g., new indication, dose regimen, addition of a new species/class). The development plan should clearly address all technical sections applicable to the supplemental approval (including CMC and Environmental Impact). CVM will not comment on information included in the submission that is not relevant to confirming the status of the technical requirements (e.g., review of study designs or protocols, which should be done under an INAD E submission);
- confirmation of the status of individual technical sections when the sponsor proposes no additional information is necessary for the approval of a B1 supplement, such as if the technical section is considered complete and the

proposal is not expected to impact the determination (e.g., CMC technical section when the formulation is not changing, or Target Animal Safety (TAS) technical section when the dosage regimen and species/class is not changing);

- confirmation of a previously agreed upon development plan, or feedback provided by CVM, for an original or B1 supplemental approval;
- confirmation of remaining technical section requirements for original or B1 supplemental approvals;
- confirmation of remaining requirements for a non-administrative NADA (180-day review timeframe) for original or B1 supplemental approvals.

IV. CONFIRMING TECHNICAL SECTION STATUS DURING THE END GAME

If the sponsor decides not to request a PSC or submit a C submission, the PM will confirm each technical section's status with the project team during the end game meeting.[6] The "end game" in this context may refer to the actual end game (CVM received the last P submission for the project) or the end game as anticipated by the sponsor (CVM received what the sponsor believes to be the last P submission) in their discussions with the PM.

V. WHEN A SPONSOR DOES NOT ADDRESS REQUIREMENTS ACROSS ALL TECHNICAL SECTIONS

For some projects, the sponsor may request a limited PSC or a limited C submission that does not address all applicable technical sections. In these cases, the PM will:

- continue to encourage the sponsor to request a PSC or submit a C submission to address the applicable technical section(s) not yet discussed.
- confirm technical section status with the project team during the end game meeting.[7] The "end game" in this context may refer to the actual end game (CVM received the last P submission for the project) or the end game as anticipated by the sponsor (CVM received what the sponsor believes to be the last P submission) in discussions with the PM.

VI. CHANGES TO PROJECT SCOPE FOLLOWING CONFIRMATION OF TECHNICAL SECTION REQUIREMENTS

When a sponsor identifies in eSubmitter that a meeting proposal represents a change to aspects of the project discussed in a previous meeting (e.g., changes to formulation, dosage form, dose, duration, route of administration, species and class, indication, or science/regulatory policy), they have the option to request revisiting their development plan across all applicable technical sections based on the change. If they choose this option, as with the first PSC, they can access templates allowing them to share their updated development plan and request input across all applicable technical sections

[6] See 1243.3051 Verifying Scope and Technical Section Status for Phased Review Investigational New Animal Drug (INAD) Projects in the End Game

[7] See 1243.3051 Verifying Scope and Technical Section Status for Phased Review Investigational New Animal Drug (INAD) Projects in the End Game

without requiring all representatives to be present for discussion in the meeting. PMs will encourage sponsors to take advantage of this option.

A sponsor may also submit their updated development plan as a C submission for written feedback from CVM. The sponsor should fully describe the proposed change to the project across all applicable technical sections.

If the sponsor chooses not to revisit their development plan across all applicable technical sections, the PM will confirm technical section status with the project team in the end game meeting. The “end game” in this context may refer to the actual end game or the end game as anticipated by the sponsor.

VII. REFERENCES

Code of Federal Regulations

Part 514 - New Animal Drug Applications

§514.5 - Presubmission conferences

§514.106 - Approval of supplemental applications

CVM Program Policies and Procedure Manual – ONADE Reviewer’s Chapter

1243.3024 Scheduling and Holding Meetings with Outside Parties

1243.3025 Preparing Meeting Documentation (i.e., Memorandum of Conference, Acknowledgement Letter, Other Review Documentation)

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

1243.4090 Processing a Sponsor Request (C Submission) for Written Feedback Regarding Development Plans for New Animal Drug Product Approvals

VIII. VERSION HISTORY

June 9, 2011 – Original version

May 13, 2019 – Updated to remove specific procedures related to PSCs which were added to 1243.3024, and to remove the requirement for the PM to hold project team meetings under a Q submission (separate from the end game meeting) when the sponsor does not request a PSC at the project’s beginning or after changing the scope.

March 20, 2021 – Updated to include the H submission option for sponsors to request written feedback on their development plans for original and Category II supplemental applications, confirmation of previous agreements, and confirmation of non-administrative NADA pathway to approval.

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

September 29, 2023 – Project management team revision to reflect submission type change that we are implementing in this process. Sponsor development plans will no

longer be submitted as an H submission under the INAD. They will now be an INAD C submission code (formerly DIAL submission). This modification is part of the October 1st CCR ONADE implementation effort. In addition, 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.