
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER’S CHAPTER

POST-BIOEQUIVALENCE TECHNICAL SECTION (POST-BETS) MEETINGS

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I. PURPOSE

This document:

- defines the scope of a post-BETS meeting,
- describes the process for scheduling and holding a post-BETS meeting for Division of Generic Animal Drugs (DGAD) reviewers, and
- includes an anticipated timeline for the post-BETS meeting.

II. BACKGROUND AND SCOPE

As part of the Animal Generic Drug User Fee Act reauthorization (AGDUFA IV), the Center for Veterinary Medicine (CVM), Office of New Animal Drug Evaluation (ONADE) agreed to establish this post bioequivalence technical section (post-BETS) meeting process to enhance review process transparency. A post-BETS meeting allows for the Division of Generic Animal Drugs (DGAD) to provide feedback to sponsors outside the context of the transmit to sponsor comments in the technical section response letter. DGAD believes it is a way to foster open communication and increase the quality of future Bioequivalence technical section submissions. It also provides sponsors an opportunity to ask questions and/or obtain clarification on CVM comments soon after the Bioequivalence technical section is closed out by CVM.

Post-BETS meetings apply only to Bioequivalence technical sections with *in vivo* study data. This program does not apply to Bioequivalence technical sections based on biowaivers.

III. STEPS FOR DGAD

1. Primary reviewer (PR) is assigned *in vivo* bioequivalence data submission (P-BQ).
2. Post-BETS meeting is scheduled internally:
 - a. Within **30 days** after the submission is assigned, the PR will schedule a 1 hour “Hold for post-BETS” with their team leader (TL) in the Outlook calendar. This should be scheduled approximately **30 days** after the Submission Tracking and Reporting System (STARS) due date of the P-BQ.

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- b. Consulting reviewers do not typically need to be included in the meeting. If the PR believes a consulting reviewer should be present in the meeting, they should discuss the situation with their TL to decide on who should be invited to the meeting.
 - c. The submission number and sponsor name should be included in the meeting invitation.
 - d. If there are scheduling issues, the PR will work with their TL to find an appropriate meeting time.
 - e. The post-BETS meeting will be virtual and limited to 1 hour; no Memorandum of Conference will be generated for the meeting.
3. Post-BETS meeting is scheduled with sponsor:
 - a. After internally scheduling the “Hold for post-BETS” meeting, the PR will email the sponsor using the post-BETS meeting scheduling email template to create an Outlook email that proposes the post-BETS meeting day and time.¹
 - b. Within **7 days** the PR should receive a response from the sponsor to the above email. The sponsor’s email will communicate one of the following:
 - i. Confirm the proposed meeting time is acceptable.
 - ii. Request to reschedule the meeting. If a reschedule is requested, the PR will work to move the post-BETS meeting to a mutually acceptable time.
 - iii. Decline the post-BETS meeting.
 - c. The PR should update the calendar meeting information to include email communication with the sponsor either confirming the time of the meeting or moving the meeting to a mutually acceptable time. If the sponsor declined the meeting, the calendar meeting should be cancelled.
 4. The PR will prepare the P-BQ review and letter documents according to applicable ONADE P&Ps² and other reviewer resources.
 - a. The templated comments in the letter will communicate the following to the sponsor:
 - i. Remind the sponsor of the previously scheduled post-BETS meeting date.
 - ii. Request the sponsor send a list of questions to the TL within 2 weeks of the date of the P-BQ letter.

¹ Internal information redacted.

² ONADE P&Ps: 1243.5820 Approval Letters, 1243.3010 Format and Style Conventions for Letters, 1243.3009 Format and Style Conventions for Reviews and Submission Summaries

- iii. Advise the sponsor to email the TL if they wish to decline the scheduled post-BETS meeting.
 - b. If applicable, at the completion of the P-BQ review, the PR will discuss if there is a need for a pre-meeting with their TL. A pre-meeting may be needed if comments are extensive or complex. The pre-meeting should be scheduled shortly after the sponsor's questions are received.
5. The PR will close out the P-BQ in Appian following established procedures. The PR will create a reminder on their calendar for 2 weeks after the sponsor is sent the P-BQ letter. The purpose of this reminder is to check-in with the sponsor to inquire if they plan to email DGAD a list of questions or decline the post-BETS meeting.
6. If applicable, once the post-BETS meeting questions are received, the TL will forward the email list of questions to the PR for discussion and meeting preparation. The PR will add the questions to be discussed to the calendar meeting.
7. If a list of questions is not received or the sponsor has not declined the meeting by 2 weeks after the P-BQ letter is sent, the PR will check-in with the sponsor and ask if they intend to send questions or would like to cancel the meeting. If the sponsor intends to send questions but cannot get them to CVM at least **10 days** before the meeting, the PR will discuss possible alternate plans, including rescheduling the post-BETS meeting, with their TL.

IV. ANTICIPATED TIMELINE

1. PR is assigned the P-BQ submission.
2. Within **30 days** of receipt of the P-BQ - The PR will send an email to the sponsor to propose a post-BETS meeting date and time.

Note: The submission is under review, the outcome is unknown and cannot be discussed at this time.

3. Within **7 days** of sending the post-BETS meeting proposal to the sponsor - The PR should receive a response from the sponsor regarding the proposal for a post-BETS meeting. The response from the sponsor will indicate one of the following:
 - Confirm availability for the proposed day and time,
 - Suggest an alternate date/time, or
 - Decline the meeting.
4. Within **14 days** of our sending the P-BQ final action letter - The TL should receive an email that contains a list of the sponsors' questions or a request to cancel the meeting.

Note: The P-BQ submission is closed out and the final action (i.e., complete or incomplete) is known at this time.

- a. CVM: Once the proposed sponsor questions have been received by DGAD, additional communication may be required to finalize the list of questions that will be discussed at the meeting.

5. Approximately **30 days** after the STARS due date of the P-BQ - The post-BETS meeting is held at the previously agreed upon time.

Note: Following the post-BETS meeting, the PR will create a Q submission for documentation purposes only if the meeting contains discussion of topics outside the scope of the P-BQ final action letter or for information that the PR or participants believe might need to be documented for future reference. In this case, the PR will create a Q submission and work with their TL to prepare documentation of the extraneous topics discussed with the sponsor or other information needed for future reference and close out the Q submission.³

V. REFERENCES

CVM Program Policies and Procedure (P&P) Manual – ONADE Reviewer’s Chapter

1243.3009 – Format and Style Conventions for Reviews and Submission Summaries

1243.3010 – Format and Style Conventions for Letters

1243.3250 – Q Submissions: Agency Initiated Actions

1243.5820 – Approval Letters

VI. VERSION HISTORY

October 13, 2023 – Original version.

³ See P&P 1243.3250 Q Submissions: Agency Initiated Actions