
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

SCHEDULING AND HOLDING MEETINGS WITH OUTSIDE PARTIES

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I. PURPOSE

This document:

- Defines the types of meetings ONADE has with outside parties, and
- Describes the procedures for scheduling and holding meetings with outside parties.

II. DEFINITIONS

A. Meeting

A meeting is any substantive oral discussion, whether by telephone, videoconference, or in person.¹

¹ Note that we do not consider brief exchanges seeking clarification to be meetings for the purpose of this document. However, you should document these exchanges in the administrative record.

B. Memorandum of Conference (MOC)

An MOC is a document prepared by ONADE personnel that documents the nature and substance of a meeting with an outside party or potential applicant. The MOC is the official record of the meeting.²

C. Outside Party

An outside party is a person(s) from outside the FDA who has requested a meeting with us. An outside party may be: 1) a potential applicant; 2) a sponsor of a food additive petition (FAP); 3) a representative of industry or a special interest group, or 4) any other external constituent.

D. Potential Applicant

Potential applicant is defined in 21 CFR 514.3.³

E. Scheduler

The scheduler is the individual in ONADE responsible for scheduling the meeting. The scheduler may be the reviewer responsible for the "Z" submission, a consumer safety officer, project manager, or other person designated by office or division procedures.

III. TYPES OF MEETINGS

A. Presubmission Conference (PS)

A presubmission conference is held to establish agreement between FDA and potential applicants regarding the number and types of studies/information required for approval. Binding agreements may be made.

B. Other Meetings (OO)

Other meetings are any meeting with ONADE other than a presubmission conference, e.g., to discuss the details of a protocol, labeling, inclusion/exclusion criteria for a data submission.⁴

² Refer to P&P 1243.3025 for details about preparing a memorandum of conference.

³ We use the term "potential applicant" with respect to presubmission conferences. We use the term "outside party" with respect to all other meetings.

Responsible Office: Office Of New Animal Drug Evaluation

Date: May 23, 2012

C. Meetings That Do Not Require "Z" Submissions

1. Divisions may discuss issues with sponsor informally over the phone and document the discussion in a Q submission (refer to P&P 1243.3250 for details about Q submissions).
2. Certain types of meetings are arranged through the Project Management Team without official "Z" submissions. These include portfolio overview meetings and lessons learned meetings. If you are unsure whether a meeting requires a "Z" submission, discuss with your team leader or a project manager.

IV. WHEN THE REVIEWER RECEIVES THE MEETING REQUEST

Meetings requested by an outside party are coded as "Z" submissions in our Submission Tracking and Reporting System (STARS).⁵ The reviewer assigned the "Z" submission should determine if the request has the correct sub-class code according to the definitions above.⁶ The reviewer should also determine if we need additional information from the outside party.

A. Presubmission Conferences

For a presubmission conference, 21 CFR 514.5(b) requires that the potential applicant submit the request in a signed letter. That letter must include a proposed agenda that clearly outlines the scope, purpose, and objectives of the presubmission conference, and lists the names and positions of the representatives who will attend the presubmission conference on behalf of the applicant.

B. Other Meetings

If the meeting is not a presubmission conference, at a minimum the outside party should provide a detailed agenda that identifies the general areas of

⁴ Note that we will not concur on a protocol in a meeting. For a formal protocol evaluation, the sponsor should submit the protocol for review.

⁵ Meetings we initiate are coded as "Q" submissions in STARS.

⁶ The reviewer can correct the sub-class code for a paper submission using the STARS Correction Form. To correct an electronic submission, the primary reviewer will need to void the submission using the STARS correction form and have the outside party resubmit using the correct sub-class code. To ensure accurate coding of electronic submissions, outside parties should work with their assigned project manager before submitting their request.

discussion and allows us to evaluate who from FDA should attend the meeting, and provide enough background information to ensure a productive meeting.

Note: We do not meet with outside parties to discuss a submission that is under review because granting such a meeting may require us to review the submission outside the normal timeframes and queues.

V. SCHEDULING A MEETING

The scheduler should:

A. Determine our invitees

In consultation with the primary reviewer or team leader, determine who to invite to the meeting. Generally, at least two people from ONADE should attend a meeting with an outside party.

B. Select a meeting date

Select a meeting date and time when the necessary attendees, an appropriate conference room, and appropriate audiovisual equipment are available, and reserve that room through Outlook.^{7,8} Generally, a meeting should not exceed two hours. If the agenda is divided into more than one meeting, schedule the meetings for the same day or over consecutive days for the convenience of out-of-town attendees.

C. Confirm the meeting

Contact the outside party and confirm the meeting date and time. After the meeting date is confirmed, submit a STARS Correction Form to change the meeting date in STARS. The STARS due date is 45 days after the date of the meeting. After confirming the due date, contact any assigned reviewers to make certain they are aware of the change of date.

⁷ We may informally agree to a tentative meeting date before the outside party submits the meeting request.

⁸ The conference room should be large enough to hold the expected attendees comfortably. The meeting should not be in an area where trade secret or commercial confidential information is stored, or where outside parties can overhear conversations involving trade secret or commercial confidential information.

D. Confirm the submission of meeting materials

Confirm that the potential applicant submitted:

- a detailed agenda,
- a copy of any materials the potential applicant will present at the conference,
- a list of proposed indications for the new animal drug,
- a copy of the proposed labeling, if available, and
- copies of materials the potential applicant evaluated or referenced relative to the issues on the agenda.⁹

The potential applicant should provide this material at least 30 calendar days before the meeting date (this minimum timeframe is required for presubmission conferences).¹⁰

E. Distribute meeting materials

Distribute materials as soon as possible so all FDA attendees have sufficient time to review the materials and prepare for the meeting. Meeting materials provided by the sponsor may be accessed directly in STARS.¹¹ Any additional materials should be distributed by the scheduler. The scheduler may have to contact the outside party and request additional information or postpone part or all of the meeting if FDA attendees determine the submitted materials are insufficient.

F. Ensure amendments are coded correctly in STARS

Ensure any additional information the outside party submits pertaining to the meeting request is coded in STARS as an amendment ("T") to the "Z" submission, and distribute it as appropriate. If an amendment is lengthy or

⁹ What constitutes a "detailed agenda" will depend on the purpose of the presubmission conference.

¹⁰ See 21 CFR 514.5(d).

¹¹ A consult and meeting materials for every attendee may not be necessary. Check with the team leader or division director. Any consulting reviews should be requested as described in P&P 1243.3200.

complex, we may need to postpone the meeting to allow ONADE participants time to review the material.

G. Determine whether a pre-meeting is needed

Determine with the primary reviewer or team leader whether we need a pre-meeting for the internal participants to discuss the agenda items and materials, and schedule it if it is necessary (see section VIII).

If there is no pre-meeting, ask the reviewer responsible for the "Z" submission to identify ONADE participants to chair the meeting and be responsible for recording the minutes.¹²

H. Assist outside party to meeting

Provide directions to the meeting location to the outside party (if necessary) and remind their representatives to arrive a few minutes early to clear security. Provide a list of the non-FDA attendees and a phone number of an office contact (escort) to the building security staff for the building in which the meeting will occur at least 24 hours before the meeting so that the security staff can prepare visitor badges more quickly.

VI. RECEIVING A CONSULT REQUEST

Consulting reviewers should review the outside party's submission materials to ensure that the information is adequate to allow for a productive discussion in their area of expertise. If the outside party did not provide sufficient information and context for a productive discussion, we may have to request additional information or postpone all or part of the meeting. Consulting reviewers should discuss the need for additional information with the primary reviewer.

VII. POSTPONING A MEETING

We should take every reasonable measure, including requesting amendments, to avoid postponing a meeting. A decision to postpone a meeting can only be made by the division director of the division responsible for the "Z" submission, after the

¹² P&P 1243.3025 discusses the responsibility for the preparation of the Memorandum of Conference and associated acknowledgement letter.

reviewer responsible for the "Z" submission, the team leader, the division director, and other ONADE participants have discussed the issue.

We should postpone a meeting if, for example:

- The meeting is a presubmission conference and the potential applicant does not submit information and materials required by regulation,
- We determine that the information the outside party submitted does not contain sufficient detail (e.g., because it does not identify specific questions, proposals, or issues, or does not explain how the materials support their position with respect to the agenda items) to have a productive discussion,
- We identify a policy issue that we need to discuss internally before meeting with the outside party, or
- Unforeseen circumstances arise that require us to postpone the meeting (e.g., the necessary meeting participants cannot attend, or meeting rooms become unavailable).

When the division responsible for the "Z" submission decides to postpone a meeting, an individual designated by that division's procedures should contact the outside party promptly to explain the reason for postponement and attempt to reschedule the meeting. If the meeting is rescheduled, the scheduler should submit a STARS Correction Form to change the meeting date in STARS, and ensure the consulting reviewers and internal meeting attendees are aware of the change.

If the meeting is canceled, we will final out the "Z" submission. Consulting reviewers should return their consult with a review or comment in Appian to the primary reviewer. The submission should be finalized out as either a submission filed with review documentation (FNR/MEMO; STARS action code 009) or with an acknowledgement letter (STARS action code 033), depending on division procedure. The memorandum or letter should be written by the reviewer assigned the "Z" submission and should explain why we did not hold the meeting.

If the outside party failed to submit the necessary information in a timely manner or if we have not resolved an internal policy issue relevant to the meeting, the individual designated by division procedures should contact the outside party by telephone and let them know that we are going to close out the "Z" submission. During that conversation, we should tell them the reason(s) for this decision, and

that we will work with them to reschedule a meeting once they submit the necessary information or once we resolve the internal policy issue. Document this telephone conversation for the administrative record.¹³ The submission should be finalized out as either a submission filed with review documentation (FNR/MEMO; STARS action code 009) or an acknowledgement letter (STARS action code 033), depending on division procedure.

VIII. HOLDING THE PRE-MEETING

We may hold an internal pre-meeting to prepare for the discussion with the outside party. The reviewer responsible for the "Z" submission should discuss with FDA participants whether a pre-meeting is necessary. If we hold a pre-meeting, we should hold it after we receive the meeting materials, and participants have had a reasonable opportunity to review these materials. When possible, the scheduler should schedule the pre-meeting at least one week before the scheduled meeting with the outside party. If needed, the basis for any decisions made during the pre-meeting discussion should be documented as appropriate.

IX. HOLDING THE MEETING

A. Signing in

The ONADE Chair should use the office template to prepare a sign-in sheet to record the attendees accurately for the meeting minutes. The Chair should provide the outside party with a copy of the completed sign-in sheet. The list of meeting participants, including the sponsor and CVM representatives, should be reflected in the preparation of the MOC.

B. Welcoming attendees

The Chair should welcome the meeting attendees, state the purpose and goals of the meeting, and remind participants of the time allotted for the meeting. The Chair should ask all participants to introduce themselves.

C. Leading the discussion

The Chair may either lead the discussion portion or turn the lead over to the outside party or another ONADE attendee. The Chair should ensure the

¹³ You may document this as a memo to the file, in your review, or in your submission summary.

meeting remains cordial and professional at all times, focus the discussion on the agenda items, and keep the meeting on schedule.

D. Summarizing the meeting

At the end of the meeting, the Chair or another attendee should recap the key discussion points, any agreements reached, and any action items identified, including assignments of responsibility. The Chair should also give the outside party the opportunity to identify items in our recap that they do not agree with. If the outside party is unfamiliar with the MOC process, we should tell them that we will send them a copy of the MOC within 45 days of the meeting.

X. POST-MEETING (FOLLOW-UP) TASKS

A. Preparation of MOC

We will prepare an MOC following P&P 1243.3025.

B. Unresolved issues

If unresolved issues remain between the outside party and us after the meeting, we may need further internal discussions or another meeting with the outside party.

XI. REFERENCES

Code of Federal Regulations (Title 21)

Part 10 – Administrative Practices and Procedures

§10.65, Meetings and correspondence

§10.70, Documentation of significant decisions in administrative file

Part 514 – New Animal Drug Applications

§514.3, Definitions

§514.5, Presubmission conferences

CVM Program Policy and Procedures Manual

1243.3025, Preparing a memorandum of conference

1243.3033, Permissible STARS action codes for STARS submissions

1243.3200, Routing a request to obtain a review of an INAD, JINAD, ANADA, or VMF submission

1243.4060, Review of protocols

XII. VERSION HISTORY

December 8, 2005 – original version

August 10, 2006 – revised to clarify the definition of other meeting approved by ONADE Management August 2006, and to add a Summary of Procedure section

May 23, 2012 – revised to reflect current practice, including changes to the administrative process due to the implementation of Appian and eSubmitter, and to remove the Summary of Procedure section since that does not follow the current template