SCHEDULING AND HOLDING MEETINGS WITH OUTSIDE PARTIES

I. PURPOSE

This document establishes our (the Office of New Animal Drug Evaluation's or ONADE's) procedures for scheduling and holding meetings with outside parties.

II. SUMMARY OF PROCEDURE

A. Determine if the meeting requested is a presubmission conference or other meeting. Any meeting in which you discuss investigational or submission requirements is a presubmission conference.

B. Determine whom to invite to the meeting.

C. Schedule the meeting.

D. Confirm the meeting and receipt of the meeting materials.

E. Distribute meeting materials to our attendees.

F. We should take every reasonable measure to avoid postponing a meeting, including asking the outside party for amendments. Only the division director of the division responsible for the "Z" submission can decide to postpone a meeting.

G. If necessary, hold a premeeting.

H. Hold the meeting.

I. Prepare the MOC and take care of any post-meeting tasks.

III. DEFINITIONS

A. Meeting

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

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]

[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.
[2] You should follow P&P 1243.3025 when you prepare the MOC.

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.

IV. TYPES OF MEETINGS

A. Presubmission Conference

A presubmission conference is one or more conferences between a potential applicant and FDA to reach a binding agreement establishing a submission or investigational requirement. Most meetings between outside parties and us are presubmission conferences. Presubmission conferences include meetings to reach agreements regarding the number and types of studies that applicants will conduct to support approval or to discuss what information an applicant will submit for review.[4]

B. Other Meetings

Other meetings are meetings to discuss topics other than submission or investigational requirements. Examples of these meetings include educational meetings and meetings about administrative processes (timing and sequencing of submissions). We generally consider meetings in which we discuss protocols in general terms or discuss an incomplete letter that we sent the outside party as

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

[4] Any meeting in which you discuss investigational or submission requirements is a presubmission conference. In those rare instance where you have already discussed with a sponsor the studies that are required and are meeting only to discuss the details of a protocol, this is not a presubmission conference. A meeting to discuss CVM comments already provided to the sponsor is not a presubmission conference, but may become one if there is discussion of future submissions because of the meeting. Nonetheless, the significant discussion points must be documented (See 21 CFR 10.70) in an MOC. Please note that you cannot reach agreements on the details of protocols in a presubmission conference or other meeting. If a sponsor wants our concurrence on a protocol, the sponsor should formally submit their protocol for review. Our procedures for how to review a protocol are in P&P 1243.4060.

"other meetings."[5] Our Document Control Unit (DCU) does not handle meetings requested by outside parties to discuss the outside parties' **project planning** for some future period. Therefore, we do not code these requests as "Z" submissions. The ONADE Project Management Team handles these meetings.

V. WHEN THE REVIEWER RECEIVES THE MEETING REQUEST

An outside party generally submits a meeting request to our Document Control Unit (DCU), who then assigns it a "Z" submission code in our Submission Tracking and Reporting System (STARS).[6] The reviewer assigned the "Z" submission should determine if the request is for a presubmission conference. If the purpose of a meeting is to discuss submission or investigational requirements, the meeting is a presubmission conference regardless of whether the potential applicant identified it as such. 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 are expected to attend the presubmission conference on behalf of the applicant.

B. Other Meetings

If the meeting is not a presubmission conference, the reviewer should request any information we need to ensure a productive meeting. At a minimum, the reviewer should request a detailed agenda that identifies the general areas of discussion and provides enough information to allow us to evaluate who from FDA should attend the meeting if the outside party did not provide one with their meeting request.

[5] A meeting in which we discuss or reach agreement that a study needs to be conducted **is** a presubmission conference. However, if a sponsor is working on a protocol, we will meet to discuss it in general terms and that is an "other meeting" as defined in P&P 1243.3024. We will not concur on a protocol in a meeting. Our concurrence on a protocol comes after a sponsor makes a submission of a protocol for review.

[6] If we initiate the meeting request, we code it as a "Q" submission in STARS.

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

VI. SCHEDULING A MEETING

When an outside party submits a meeting request to the DCU or the designated electronic submissions mailbox, DCU will log it into STARS and code it as a "Z" submission. To schedule the meeting the scheduler should:

A. Determine our invitees

In consultation with the primary reviewer for the submission or team leader, you should determine who we need 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

You should select a meeting date and time when the necessary attendees, an appropriate conference room, and appropriate audiovisual equipment are available, and reserve that room.[7,8] Generally, a meeting should not exceed two hours. If you have to divide the agenda into more than one meeting, you should schedule the meetings for the same day or over consecutive days for the convenience of out-of-town attendees.

C. Confirm the meeting

You should contact the outside party and confirm the meeting date and time. After you set the meeting date, you should contact a supervisor in the DCU, either by email or by going to the DCU, and ask them to reset the due date for the "Z" submission for 45 days after the meeting date.[9] STARS automatically adjusts the

[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.
[9] You may either send the entire package back to the DCU or hand carry it to get the new STARS cover sheet showing the new due date.

due date, however you must change your DCU Routing Slip manually, or ask the DCU to prepare a new DCU Routing Slip for you. After you confirm the due date, contact the primary reviewer, and if you have distributed the consulting review requests any consulting reviewers, to make certain they are aware of the change of date.

D. Confirm the submission of meeting materials

For a presubmission conference, you should 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.[10]

The potential applicant must provide this material at least 30 calendar days before the meeting date.[11]

E. Distribute meeting materials

You should distribute materials as soon as possible after we receive them so all FDA attendees have sufficient time to review the materials and prepare for the meeting. You should send meeting materials to each ONADE attendee as a consulting review request through the DCU and STARS.[12] You may have to contact the outside party and request additional information or postpone part or all

[10] What constitutes a "detailed agenda" will depend on the purpose of the presubmission conference.
[11] See 21 CFR 514.5(d).
[12] A consult and meeting materials for every attendee may not be necessary. In some cases, you may provide meeting materials without sending a consulting review request through STARS. If you do request a consulting review, you should follow P&P 1243.3200. Check with your team leader or division director.

of the meeting if FDA attendees determine that the materials the outside party submitted are insufficient.

F. Ensure meeting materials are coded correctly in STARS

You should ensure that the DCU codes any additional information the outside party submits pertaining to the meeting request into STARS as an amendment ("T") to the "Z" submission, and distribute it as appropriate. If the amendment is lengthy or complex, we may need to postpone the meeting to allow ONADE participants to review the material.

G. Determine if a pre-meeting is needed

You should determine, in consultation with the primary reviewer or team leader, if 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, you should ask the reviewer responsible for the "Z" submission to identify ONADE participants to chair the meeting and be responsible for recording the minutes.[13]

H. Assist outside party to meeting

You should 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. You should 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.

VII. RECEIVING A CONSULT REQUEST

If you receive a consulting review request or a meeting request through STARS, you will get a copy of the submission (i.e., electronic or hard copy). When you receive the

[13] Typically, a Consumer Safety Officer (CSO) will be responsible for recording the minutes of the meeting so that reviewers can devote their complete attention to the discussions. P&P 1243.3025 discusses the responsibility for the preparation of the Memorandum of Conference and associated acknowledgement letter.

request, you should review the outside party's submission materials to assure that the information is adequate to allow for a productive discussion in your 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 (see section VII below). You should discuss the need for additional information with the reviewer responsible for the "Z" submission.

VIII. POSTPONING A MEETING

We should take every reasonable measure to avoid postponing a meeting, including asking the outside party for amendments. A decision to postpone a meeting can only be made by the division director of the division responsible for the "Z" submission, after the 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 you reschedule the meeting, you should contact the DCU and ask them to reset the review clock for the "Z" submission based on the new meeting date. You

should also contact the consulting reviewers and internal meeting attendees to make certain they are aware of the change.

If the outside party and we agree that it is not necessary to reschedule the meeting, we will final out the "Z" submission. Consulting reviewers should return the consulting review through STARS to the primary reviewer. The submission should be finaled 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.[14] 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.[15] The submission should be finaled 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.[16]

IX. HOLDING THE PRE-MEETING

We may hold a pre-meeting to review the meeting materials and history of related relevant submissions or to discuss any issues or questions about items on the agenda. 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.

[14] You should follow P&P 1243.3033, and use the final action code that is appropriate.
[15] You may document this as a memo to the file, in your review, or in your submission summary.
[16] You should follow P&P 1243.3033, and use the final action code that is appropriate.

At the pre-meeting, participants will determine who will chair the meeting with the outside party and who will record minutes of that meeting. A CSO or other participant should document the talking points developed for the meeting with the outside party and the basis for any decisions made during the pre-meeting.[17] You should place all pre-meeting documentation in the administrative file either as a separate document or as part of a review under a "Pre-meeting" heading.

X. HOLDING THE MEETING

A. Signing in

The ONADE Chair should provide 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 sign-in sheet. All divisions should prepare a standard pre-printed sign-in sheet.

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 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 the person recording the minutes should recap the key discussion points, agreements, and action items, including

[17] FDA regulations, 21 CFR 10.70, require FDA employees responsible for a matter to insure the completeness of the administrative file by documenting significant decisions. A meeting solely to discuss administrative matters, e.g. who will chair the meeting or who will take minutes, is not a pre-meeting and need not be documented.

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.

E. Preparing an MOC

We prepare an MOC for most meetings.[18] If we will prepare an MOC, we should tell the outside party that:

- we will send them a copy of the MOC within 45 days of the meeting and final out the meeting request,
- they may submit a request for substantive corrections or clarification of information in the MOC (they must do this within 30 days from the date of our letter), and
- we will file any minutes the outside party submits; however, we will not reply and will not review the outside party's minutes for accuracy.

XI. 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.

XII. REFERENCES

Code of Federal Regulations (Title 21)

Part 10 – Administrative Practices and Procedures

[18] 21 CFR §514.5(f) requires us to prepare an MOC for presubmission conferences.

§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

XIII. 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