OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PREPARING MEETING DOCUMENTATION (I.E., MEMORANDUM OF CONFERENCE, ACKNOWLEDGEMENT LETTER, OTHER REVIEW DOCUMENTATION)

I. PURPOSE

This document:

- Defines a Memorandum of Conference (MOC)
- Describes what information to include in an MOC, MOC acknowledgment letter, and internal documentation related to meetings
- Explains the responsibilities of the preparer,[1] assigned consulting reviewers,[2] and other meeting participants[3]
- Includes timeframes for preparing, commenting on, and finalizing meeting documentation
- Describes how to handle correspondence from the sponsor following the meeting
- Provides information on presubmission conference agreements
- Describes options for documenting concurrence on meeting documentation

II. DEFINITION OF AN MOC

An MOC is a document prepared by Office of New Animal Drug Evaluation (ONADE) personnel that documents the nature and substance of a meeting with an outside

[1] The preparer is the primary reviewer (PR) assigned to the "Z" submission or any other individual designated by office, division, or team procedures as responsible for preparing the meeting documentation.
[2] A consulting reviewer is an individual assigned a consulting review through our Submission Tracking and Reporting System (STARS).
[3] Other meeting participants are individuals from CVM who participate in the meeting without having formal consults through STARS.

party[4] (referred to as the "sponsor" through the remainder of this document). The MOC is the official record of the meeting, and CVM issues a copy to the sponsor accompanied by an acknowledgment letter.

An MOC must provide enough detail to allow individuals reading the MOC now and potentially years later to understand the nature and substance of the meeting. It should not be a transcript of the meeting. The scope of an MOC is limited to discussions and information exchanged during the meeting, including any agreements reached and action items identified. Any additional information CVM wishes to transmit to the sponsor will be included in the acknowledgment letter that accompanies the MOC, rather than in the MOC itself.

III. WHEN AN MOC IS REQUIRED

An MOC is generally required for all (J)INAD and (A)NADA meeting requests when a meeting is held. Meeting requests are identified in our Submission Tracking and Reporting System (STARS) as "Z" submissions. There are three meeting types:

1. A presubmission conference (PS),[5]
2. A method demonstration (MD), and
3. Other ONADE meeting (OO).

An MOC is <u>always</u> required for a presubmission conference. As an ONADE employee, you are required to document the substance of any other meeting with a sponsor when you determine that such information will be useful.[6] You may document an informal meeting or discussion (unrelated to a "Z" submission) with a memo to file ("Q" submission), or if the discussion is related to a pending submission, as part of the review documentation prepared for that pending submission. This type of documentation is not considered an MOC and does not fall under this P&P.

IV. CONTENT OF THE MOC, ACKNOWLEDGEMENT LETTER, AND INTERNAL DOCUMENTATION

A. MOC

Prepare the MOC using the office template and include the following information:

1. List of attendees, with affiliation

   For CVM attendees, identify their affiliation within CVM at the time of the meeting and include managers' administrative titles (e.g., division director). Do not use acronyms. Do not use mail codes ("HFV-") because they are subject to change and do not provide adequate identification.

[4] An outside party is a person(s) from outside the FDA who has requested a meeting with us. An outside party may be a potential applicant, a representative of industry or a special interest group, or any other external constituent.

[5] See §514.5(f)(1). "Presubmission Conference" means one or more conferences between a potential applicant and FDA to reach a binding agreement establishing a submission or investigational requirement.

[6] <u>See §10.65(e).</u>

For sponsor attendees, identify their company or organization affiliation. If the meeting included someone acting as the sponsor's US agent, identify that person by following their name with the term "US agent."

Delete any unused rows from the table of attendees or add rows if necessary.

2. Background pertinent to the request for the meeting

   In the first paragraph of the MOC, state who requested the meeting and the general topics for discussion. Subsequent paragraphs may briefly describe any background information pertinent to the request for a meeting and any other information that is necessary to ensure the completeness of the administrative file. For example, it may be appropriate to include information about other submissions received before the request for meeting that relate to the meeting agenda, product information, or proposed indications. Do not include information in this section that we cannot share with the sponsor, such as other sponsors' proprietary information.

3. Summary of key points of discussion

   Use appropriate headings to form an outline and add subheadings as needed (examples of headings include technical sections or the sponsor's agenda items). Briefly summarize the main points discussed at the meeting for each item. For presubmission conferences at which technical sections were confirmed to be complete during the meeting, the sponsor will provide a copy of the MOC from the meeting in lieu of a technical section complete letter when they submit their application for approval.[7]

4. Presubmission Conference Agreements section[8]

   Presubmission conferences are the only meetings in which agreements may result. If the meeting is not a presubmission conference, delete this section from the MOC.

   If an agreement on any investigational or submission requirement was reached during the presubmission conference, include enough detail in this section to ensure the terms of the agreement are clear; for example, include any conditions associated with the agreement. Carefully consider what to include in this section; these must be specific agreements on submission or investigational points that will allow us to make a determination about safety or effectiveness. There are different technical sections built into the template in the Presubmission Conference Agreements section. Delete any that do not apply and add a "Chemistry, Manufacturing, and Controls" technical section when needed. Note that human user safety and abuse potential are captured under the "Target Animal Safety" technical section.

[7] Refer to P&P 1243.3024 "Scheduling and Holding Meetings with Outside Parties" for more information.
[8] Refer to Appendix 1 for additional information about presubmission conference agreements.

If no agreements were reached during the presubmission conference, replace all template text within the Presubmission Conference Agreements section with the text, "There were no agreements."

5. Action Items section

   List any items requiring further action or clarification. For each item, include the responsible party (CVM or the sponsor) and when/how the action item will be addressed (for example, in the acknowledgment letter accompanying the MOC, through email following the meeting, etc.). If there were no action items, enter text in this section stating, "There were no action items."

B. Acknowledgement Letter

Use the office template to prepare the acknowledgment letter that will accompany the MOC. The acknowledgment letter may include additional comments that CVM wishes to communicate to the sponsor following the meeting. For presubmission conferences in which CVM provides confirmation only through written comments (not during the discussion) that technical sections are complete, the sponsor will provide a copy of the acknowledgment letter in lieu of a technical section complete letter when they submit their application for approval.[9]

C. Submission Summary, Review, or Other Internal Documentation

The preparer will document concurrence from assigned consulting reviewers, as well as other CVM participants if desired, in a review, submission summary, or other review-related documentation. There are different ways to document concurrence (e.g., record individual email responses and attach those to the review prepared for the "Z" submission, provide a general statement in the review that says each CVM participant was contacted and concurred on the prepared meeting documentation, etc.). The specific way concurrence is documented will vary depending on the level of discussion and editing that ensue following the meeting. Discuss with your supervisor which methodology is best for your particular situation.

There are times when review documentation, such as a submission summary or review, might not be required. Those instances are rare and would be for situations where no internal discussions were required to prepare for the meeting. This is allowed because no documentation is needed for FDA's record other than what happened at the meeting with the sponsor. It is still necessary to document concurrence on the MOC and acknowledgment letter. One way to accomplish this is provided in Appendix 2.

A submission summary is typically required, either as a stand-alone document or as part of a review document generated by the preparer. The preparer will generate a review if it is needed to ensure the completeness of the administrative file. Consulting reviewers will also write reviews if needed for completeness of the file. For example, if examination of background materials and decisions relating to the meeting need to be documented, or if information related to the meeting that

[9] Refer to P&P 1243.3024 "Scheduling and Holding Meetings with Outside Parties" for more information.

cannot or will not be transmitted to the sponsor in the MOC or acknowledgment letter needs to be captured, it will be included in a review. See P&P 1243.3009 "Format and Style Conventions for Reviews and Submission Summaries" for information on format and style conventions for a scientific review. Reviews may include, among other items:

1. A review or summary of background materials examined
2. Background information that cannot be provided in the MOC for proprietary reasons, e.g., recommendations about a specific issue based on previous submissions or related applications belonging to other sponsors
3. Chronology of relevant events or actions following the meeting, e.g., need for correction of information provided to the sponsor at the meeting, or completion of action items
4. Status of technical sections
5. References to other related meetings, such as pre-meetings
6. A summary or record of further internal discussions that bear on the substance of the MOC or acknowledgment letter or lead to additional comments or recommendations in the acknowledgment letter
7. A "Transmit to Sponsor" section, with additional comments to be included in the acknowledgment letter if applicable
8. The basis for any decision(s) not previously documented

V. PROCESS, RESPONSIBILITIES, AND TIMEFRAMES FOR PREPARING AND REVIEWING MEETING DOCUMENTATION

CVM has **45 days** from the date of the meeting to issue the acknowledgment letter and a copy of the MOC to the sponsor.[10] Because the times allotted for preparing, circulating, and concurring or commenting on the documentation, and closing out the "Z" submission, are relatively brief, it requires a collaborative effort. Individuals are expected to provide their text and concurrence or comment within the timeframes described below; a summary table of the timeframes is included at the end of this section.

Note: If the review team determines during the pre-meeting that input from a consulting reviewer is not needed after all, that consulting reviewer will not contribute to the preparation of the documentation and therefore does not need to be included in the review and concurrence stage.

A. Determine How Meeting Documentation Will Be Generated and Reviewed

1. The preparer and any consulting reviewer(s) will determine who will be responsible for writing which portions of the MOC and how comments will be shared. Generally, consulting reviewers will prepare the portion of the MOC

[10] See §514.5(f)(1)(ii).

related to their specialty because their expertise is critical to accurately documenting the discussion.

a. Determine the role of other meeting participants, if applicable

   i. For other participants from a consulting reviewer's team or division, the consulting reviewer will determine with them:

      - How they will consolidate and provide information to be included in the documentation (through email or posted in a shared location);
      - How they will resolve conflicting comments within their team or division;
      - Who will review the documentation, how they will provide comments to the consulting reviewer, and how the consulting reviewer will resolve any conflicting comments before returning concurrence or concurrence with comment to the preparer

   ii. For other participants not from a consulting reviewer's team or division, the preparer will determine with them whether and how they will contribute to the meeting documentation.

b. Determine whether to designate a "lead" consultant

   In some cases, multiple consulting reviewers will contribute to a single portion of the MOC. For example, a presubmission conference "Effectiveness" portion may include text from the target animal division (TAD), biostatistics, and clinical pharmacology teams. In such a case, the reviewers may designate a "lead" consultant (in this example, it would be a TAD reviewer) and other consultants will provide their text to the designated lead consultant. The lead consultant will work with the other consultants, following team and division clearance procedures, to confirm the text to be provided to the preparer.

2. The preparer will provide consulting reviewers, and other meeting participants if desired, with a table showing the steps and associated due dates for processing the documentation, following the summary of timeframes at the end of this section.[11]

B. Generate Meeting Documentation and Circulate for Review

1. The preparer will generally record the key discussion points, agreements, and action items during the meeting, even if consulting reviewers agreed to prepare their portion of the MOC. The preparer, using notes taken during the meeting, will begin drafting the documentation as soon as possible after the meeting.

[11] An Excel timeline template is available on the ONADE templates page.

2. If consulting reviewers are providing text to a "lead" consultant, they will provide that text no later than **10 days** from the date of the meeting.

3. Consulting reviewers, and other meeting participants if desired, will provide to the preparer, if they are writing their portion of the MOC, the key discussion points, agreements, and action items relating to their area of specialty, and any additional comments they want communicated to the sponsor in the acknowledgment letter. This may be done through email or a returned consulting review no later than **21 days** from the date of the meeting. The text provided to the preparer will incorporate comments received from other team or division participants, as appropriate, and will be cleared through the appropriate management chain.

   If a "lead" consultant is working with other consultants to confirm text, they will provide that text to the preparer by the day 21 deadline.

   If consulting reviewers are writing a review and have agreed to prepare their section of the MOC, the consulting review will include:

   a. Their portion of the MOC.

   b. Any additional comments they want transmitted to the sponsor in the acknowledgment letter. These comments will be included in the review under the "Transmit to Sponsor" section and identified as "Additional comments to be communicated to the sponsor in the acknowledgment letter."

   Consulting reviews will be returned to the preparer through Appian no later than **21 days** from the date of the meeting, following the consulting reviewer's team and division clearance procedures.[12]

4. The preparer will draft the MOC and acknowledgment letter as described above, incorporating the sections written by consulting reviewers when applicable. The preparer will generally incorporate the information provided by consulting reviewers verbatim, although the preparer may make minor editorial changes such as defining acronyms and ensuring consistency of the sponsor's or product's name throughout the documentation. The preparer must discuss any proposed substantive changes with the appropriate consulting reviewer(s) before incorporating them.

   The preparer will clear the draft documentation through the appropriate management chain, then distribute it to the consulting reviewers, and other meeting participants if desired, for concurrence or comment no later than **28 days** from the date of the meeting. Documentation may be distributed for comment through email or posted in a shared location for changes or comments to be entered directly.

C. Review and Concur or Comment on Meeting Documentation

[12] These procedures will be consistent with P&P 1243.3029, "Closing Out a Consulting Review for STARS Submissions."

Consulting reviewers, and other meeting participants if desired, will review the documentation and respond to the preparer that they either:

1. Concur with the documents as written, or

2. Concur with the documents if the provided revisions are made.

Consulting reviewers will refrain from making edits to any text other than that which they initially prepared, but may recommend revisions to other sections, using tracked changes or comment bubbles, for the respective consulting reviewer's consideration. Consulting reviewers will make any agreed-upon revisions to their own section themselves. Consulting reviewers, and additional participants if desired, will provide concurrence or concurrence after revisions no later than 35 days from the date of the meeting.

Note: Typically, the preparer sends the MOC only to consulting reviewers, copying their team leaders, and the consulting reviewers may distribute it to other participants in their team or division. If a consulting reviewer has determined that others from their team or division will comment on the MOC, the consulting reviewer will follow the process established before the meeting to evaluate the comments received from those team or division participants to determine which comments they will provide to the preparer. These comments will primarily address their area of specialty and be documented in a manner that ensures the completeness of the administrative file.[13] In the event that consulting reviewers from different groups (ex: target animal division, biostatistics, and clinical pharmacology teams; or target animal division and division of manufacturing technologies teams) need to coordinate text for overlapping or interrelated concepts, they will work together to finalize the text before returning concurrence or concurrence with comments.

D. Finalize the Meeting Documentation and Close Out the Submission in Appian

1. The preparer will finalize the meeting documentation, incorporating revisions from consulting reviewers as appropriate and making any other necessary final changes to the documentation. The preparer will resolve any conflicting revisions with the appropriate consulting reviewers and document the resolution if needed to ensure the completeness of the administrative file. The preparer will only accept revisions in sections that were made by the consulting reviewer assigned to that section. If edits were made by other consulting reviewers, the preparer will notify the consulting reviewer assigned to that section and obtain their concurrence or comments on the revisions before moving forward. The preparer may opt to have an additional round of concurrence with the appropriate consulting reviewers if needed.

2. The primary reviewer will close out the submission through Appian no later than **45 days** from the date of the meeting. The primary reviewer will generally upload the following documents into Appian (consulting reviews

[13] See P&P 1243.2010, "Responsibilities for Creating and Keeping Records."

returned through Appian will automatically be included as part of the final action package):

a. The MOC

b. The acknowledgment letter

c. A submission summary, as a standalone document or as part of a review. This will include supporting documentation as needed to ensure the completeness of the administrative file (for example, emails documenting resolution to internal discussions) and concurrence from the consulting reviewers.

The primary reviewer and the appropriate management chain must sign off in the clearance chain for the MOC and acknowledgment letter in Appian.[14] Note that signatures on the MOC are not transmitted to the sponsor but are maintained on an internal copy.

E. If Applicable, the Preparer Will Remind Those Assigned the Responsibility for Any Action Items to Follow Up on Their Action Items Within the Agreed-Upon Timeframes

F. Responsibility of Team Leaders and Division Directors

Team leaders and division directors are collectively responsible for ensuring that the final documents are complete, easily understandable by the sponsor, and accurately represent the discussion in the meeting. This is particularly important for MOCs for presubmission conferences because presubmission conference agreements are binding on the sponsor and CVM. A thorough review of the documents should also minimize the need for sponsors to request revisions to an MOC.

[14] See §10.70(c)(2).

G. Summary of Timeframes

Clock Day	Task
Day 10	Consulting reviewers provide draft text to designated "lead" consultant (when applicable)
Day 21	Consulting reviewers provide MOC section, comments for letter to preparer
Day 21	Consulting reviewers close consult through Appian
Day 28	Preparer circulate documents to consulting reviewers
Day 35	Consulting reviewers provide concurrence or concurrence after revisions
Day 45	Primary reviewer close out final action package

VI. HANDLING CORRESPONDENCE SUBMITTED BY THE SPONSOR

Correspondence from the sponsor directly related to the MOC is coded as a "Y" submission in STARS. If the sponsor addresses action items that resulted from the meeting, or has questions about their next steps, the submission is not directly related to the MOC and should be coded and handled in a manner appropriate to the nature of the submission. The primary reviewer will determine the appropriate final action based on the purpose of the submission.

A. Submission of Sponsor Meeting Minutes

If the sponsor submits only their version of the meeting minutes, the primary reviewer will close out the submission in Appian using the final action "Submission filed with no review documentation; no letter sent."

B. Request to Revise the MOC

A request for changes to a presubmission conference MOC must be sent within 30 days of the date CVM issued the MOC; other meeting types do not have a specified timeframe for requesting changes. If the sponsor requests revisions to the MOC, the preparer will route the submission to the appropriate consulting reviewers. CVM has **45 days** from the receipt of the request to respond to the sponsor.[15] Therefore, the preparation and review of an acknowledgment letter responding to the sponsor's request, and an amended MOC if necessary, will follow the procedures and timeframes (using the date of receipt of the request) described for the original MOC.

Use the amended MOC acknowledgement letter template to respond to this submission, either informing the sponsor that we have not made any changes to

[15] See §514.5(f)(1)(iii).

the original MOC or summarizing the changes that were made in response to the request. If changes to the MOC are necessary, the preparer will generate an amended MOC with the title, "Amended Memorandum of Conference" and with the appropriate "Y" submission identifier. The preparer will also reissue any comments from the acknowledgement letter accompanying the original MOC in the acknowledgement letter accompanying the amended MOC, so the sponsor has a complete set of information in these documents.

Determine whether to generate a submission summary, review, or other internal documentation according to the principles outlined above in section IV.C. As explained in that section, it is important to document concurrence and to ensure the completeness of the file.

VII. REFERENCES

Code of Federal Regulations

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

1243.2010 – Responsibilities for creating and maintaining records

1243.3009 – Format and style conventions for reviews and submission summaries

1243.3024 – Scheduling and holding meetings with outside parties

1243.3029 – Closing out a consulting review for STARS submissions

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

VIII. VERSION HISTORY

November 10, 2004 – original version

August 10, 2006 – revised to update and change consulting review timeframe to 21 days, add a Summary of Procedure section, remove the sample letter because the office now uses a template, and make other clarifications agreed upon by ONADE Management.

December 4, 2008 – revised to clarify that there are only two copies of the MOC prepared. One copy on white paper, which serves an enclosure and accompanies the

letter, and the other on pink paper. The pink copy contains administrative information and is for the administrative record. Section II. Summary was removed as this is no longer our standard format.

May 11, 2012 – revised to reflect current practice, including changes to the administrative process due to the implementation of Appian and eSubmitter

September 4, 2012 – revised to incorporate minor edits

September 10, 2014 – revised to update the internal timeframes associated with completing an MOC to reflect a single round of review, with more time allotted earlier in the process for consolidating text among different assigned consulting reviewers and clearing text through the appropriate management chain; minor edits made in other portions of the text.

November 4, 2014 – removed text added September 10, 2014, which indicated that attendees' degrees should not be listed.

July 8, 2016 – minor revisions to formatting and content.

September 21, 2017 – revisions to provided information on how to document concurrence using Outlook email, appendix added to provide detailed information on presubmission conference agreements, and other updates. Internal information redacted from internet version.

January 6, 2020 – revised to clarify meeting types, update the P&P reference for written feedback from consultants not expected to attend the meeting, to move Outlook email concurrence steps to an Appendix, and to incorporate overlapping information from different sections into single sections.

January 14, 2020 – revised to clarify current process for preparing documentation for meetings. The title of the P&P was also changed for clarification purposes. Title was changed from "Preparing a Memorandum of Conference (MOC)" to "Preparing Meeting Documentation (i.e., Memorandum of Conference, Acknowledgement Letter, Other Review Documentation)".

July 19, 2021 – Updated to include the numbering in the list in Appendix 1, section J. Also, updated to fix minor spelling errors.

August 4, 2021 – Updated Appendix 1, Section G to remove the reference to the office policy since it was incorporated into P&P 1243.3024 Scheduling and Holding Meetings with Outside Parties.

APPENDIX 1: PRESUBMISSION CONFERENCE AGREEMENTS

A. Background

Section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (incorporated as part of the Animal Drug Availability Act of 1996) establishes an entitlement for a potential applicant[16] to hold one or more conferences with us to reach agreement as to certain submission or investigational requirements *before the application* is submitted (hence the name, presubmission conferences). These presubmission conference (PSC) agreements are intended to be binding on both parties unless there is a mutual agreement to make a change to such an agreement, or we determine that a substantial scientific requirement (appearing after the agreement was reached) is essential to a determination of safety or effectiveness and issue a written order to that effect.

B. Which Technical Sections Are Subject to PSC Agreements?

The Act is specific to only those potential agreements that may be reached regarding safety and effectiveness requirements.

Language from the preambles to the proposed (65 FR 51782) and final (69 FR 51162) clarify that safety can include *target animal safety* and *human safety*. Therefore, all aspects of human safety (e.g., human food safety, human user safety and human abuse potential) are subject to PSC agreements. Because the quality of the drug product underlies a product's safety and effectiveness, chemistry, manufacturing and controls (CMC) are also subject to PSC agreements.

The PSC requirements in the Act did not extend to any obligations that we have under the National Environmental Policy Act of 1969 (NEPA).

Therefore, PSC agreements may be reached for all major technical sections except for Environmental Impact.

C. Are Generic New Animal Drugs Subject to PSC Agreements?

Yes, the pre-submission conference regulation (21 CFR 514.5) applies to both NADAs and ANADAs. In fact, section 514.5(b) states that "a potential applicant is entitled to one or more conferences prior to the submission of an NADA, supplemental NADA, or an ANADA to reach an agreement establishing part or all of a submission or investigational requirement."

Because the bioequivalence study acts as a proxy for determining the safety and effectiveness of the generic new animal drug it is an appropriate subject of PSC agreements.

D. Which Agreements in PSCs Should Be Considered PSC Agreements?

The implementing regulations at 21 CFR 514.5(e) describe PSC agreements as "… submission or investigational requirement [that] may include, among other things, the number, types, and general design of studies that are necessary to

[16] Potential applicant is defined in 21 CFR 514.3.

demonstrate the safety and effectiveness of a new animal drug for the intended uses and conditions of use prescribed, recommended, or suggested in the proposed labeling for the new animal drug."

For the purposes of Office-wide consistency and implementation, PSC agreements are considered those high-level agreements on *the number and types of studies* the potential applicant will submit. Because the process-driven nature of drug manufacturing, most PSCs will not result in a PSC agreement for CMC but can be used when appropriate (e.g., see example 8 in Section J below).

While we may reach understandings or agreements with the potential applicant on many other aspects of the major technical sections, including environmental impact, and for labeling, indications, etc., documentation of these other agreements would be in the body of the memorandum of conference (MOC) and would not be included in the "Presubmission Conference Agreement" section (see examples below). So, for example, an agreement to conduct a particular type of study would typically be a PSC agreement. Details of the study design may be discussed in the PSC and documented in the body of the MOC but would not typically rise to the level of a PSC agreement.

E. Where Are PSC Agreements Documented?

Agreements regarding the number and types of studies in a PSC must be included in the MOC under a heading entitled "Presubmission Conference Agreement." See the MOC template on the ONADE Templates SharePoint page. The reviewer(s) for each technical section discussed in the meeting should include with their MOC text any agreements reached for their technical section.

F. Why Pull Out Points Which Have Already Been Discussed and Documented in the Body of the MOC and Repeat Them in the PSC Agreement Section?

The regulation specifically states at 21 CFR 514.5(f)(1)(i): "If the presubmission conference agreement section of the memorandum is silent on an issue, including one that was discussed in the conference or addressed by materials provided for the conference, such silence does not constitute agreement between FDA and the potential applicant on the issue." In other words, anything not pulled out and listed in the agreements section of the MOC is not a formal PSC agreement. The goal of this policy is to get Office-wide consistency on how we document PSC agreements in the MOC.

G. What if There Are No PSC Agreements?

The goal of PSC meetings is to reach agreements, where possible. See P&P 1243.3024 Scheduling and Holding Meetings with Outside Parties for more information about the importance of PSC agreements. However, if no such agreements are reached, state that there were no agreements in the Presubmission Conference Agreements section of the MOC.

H. Do We Need Verbal Agreement From the Potential Applicant in the Meeting to Call it an Agreement?

Yes. At the close of each presubmission conference or at the end of a technical section discussion if the CVM participants leave the meeting early, CVM needs to summarize the key points of discussion, any PSC agreements, and action items (see P&P 1243.3024 Scheduling and Holding Meetings with Outside Parties). The primary reviewer (PR) for the meeting is responsible for ensuring enough time is allotted in the meeting agenda for this summary. This summary of key points will provide the potential applicant with the first and best opportunity to agree, request clarity or disagree and, therefore, ensure that the discussions and any PSC agreements reached will be accurately documented in the MOC.

I. What Should You Do if You Are Not Sure if an Agreement at a Meeting Falls Under the Definition of a PSC Agreement?

Talk with your team leader and the PR. Use the examples below as a guide. However, the examples below will not cover every situation. If you have a specific situation where there is doubt as to whether an agreement is a PSC agreement, you should not include it in the PSC agreements section. The goal of this policy is to get Office-wide consistency on documenting PSC agreements, not to include items in the PSC agreements section that do not rise to the level of a PSC agreement.

J. Examples

Below are several clarifying examples of what should or should not be included in a "Presubmission Conference Agreement" portion of the MOC documenting a meeting with a potential applicant.

The following examples would be considered PSC agreements:

1. We agree a standard margin of safety study (e.g., "1, 3, 5X study") will be conducted.

2. We agree the standard battery of studies to support human food safety as outlined in GFI #3 will be conducted.

3. We agree a laboratory model study plus a systematic review of the literature and meta-analysis will be conducted to demonstrate substantial evidence of effectiveness.

4. We agree a blood-level bioequivalence study will be conducted for a generic new animal drug.

5. We agree a systematic review of the literature will be conducted to support human user safety.

6. We agree a specific battery of studies will be conducted to address human abuse potential.

7. We agree with a potential applicant's proposal to address a major technical section but only with specific caveats (the PSC agreement section should refer to the list of caveats discussed in the body of the MOC).

8. We agree no new submission is required to support human food safety, target animal safety, effectiveness or CMC (e.g., the technical section is not affected by a supplemental change or a potential applicant can reference a completed technical section from another application). Refer to P&P 1243.3050 Determining Technical Section Requirements for New Animal Drug Product Approval. The potential applicant will submit a copy of the MOC from this meeting in lieu of a technical section complete letter when they submit their application.

The following examples would not be considered PSC agreements but should be documented in the body of the MOC:

1. The potential applicant makes a proposal for demonstrating effectiveness and we believe the potential applicant is on the right track, but we request that the potential applicant provide additional information before we can agree.

2. We have general discussions on human abuse potential but refer the potential applicant to CDER for details on what types of studies will be required.

3. We agree that the potential applicant may submit a request for a categorical exclusion to address environmental impact.

4. We agree with the potential applicant's proposed proprietary name.

5. We agree with the wording of the potential applicant's proposed indication.

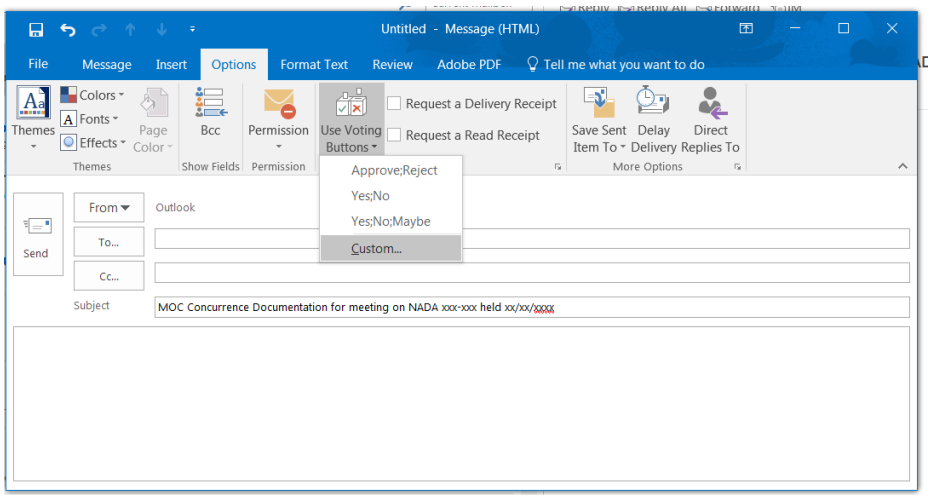
6. We agree with specific wording for the product labeling.

7. We agree to specific details of study design, e.g., number of animals, primary variable, statistical analysis, etc.

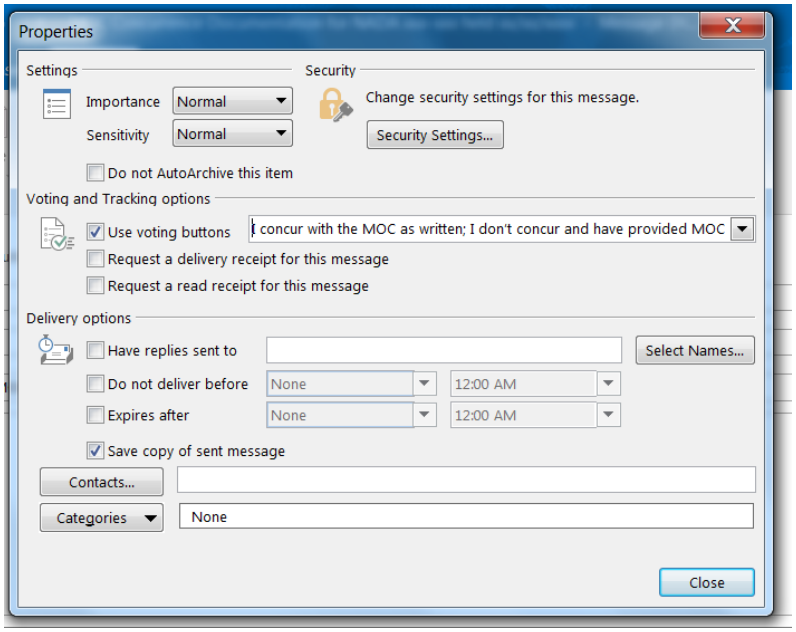
APPENDIX 2: HOW TO DOCUMENT CONCURRENCE USING OUTLOOK

1. To generate Concurrence Documentation using Outlook, generate a new email message. In the "To" recipient field, enter the names of all the consulting reviewers and CVM participants. Add an appropriate title (such as "MOC Concurrence Documentation for meeting on NADA xxx-xxx held xx/xx/xxxx" or "MOC Concurrence Documentation for INAD-xxx-xxx-Z-xxxx held xx/xx/xxxx), and then select "Options" on your email toolbar.

2. Click "Use voting buttons" and then select "Custom".



3. The properties window will open. Check the "Use Voting Buttons" box and insert the following (including semicolons) to be the voting options: Concur with the MOC as written; Concur with the documents if the provided revisions are made. Then, click the "Close" button.



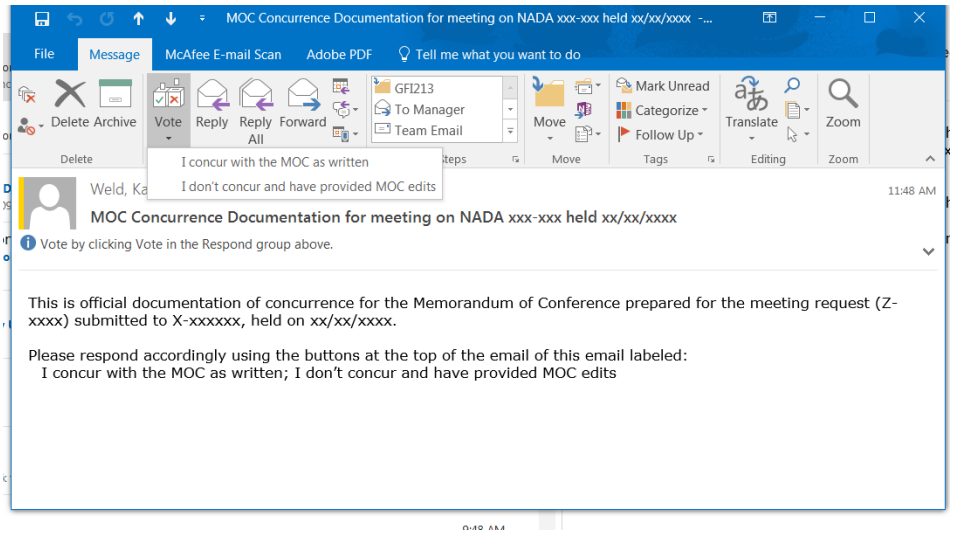
4. In the body of the email, type-in or copy the following language:

   This is official documentation of concurrence for the Memorandum of Conference prepared for the meeting request (Z-xxxx) submitted to X-xxxxxx, held on xx/xx/xxxx.

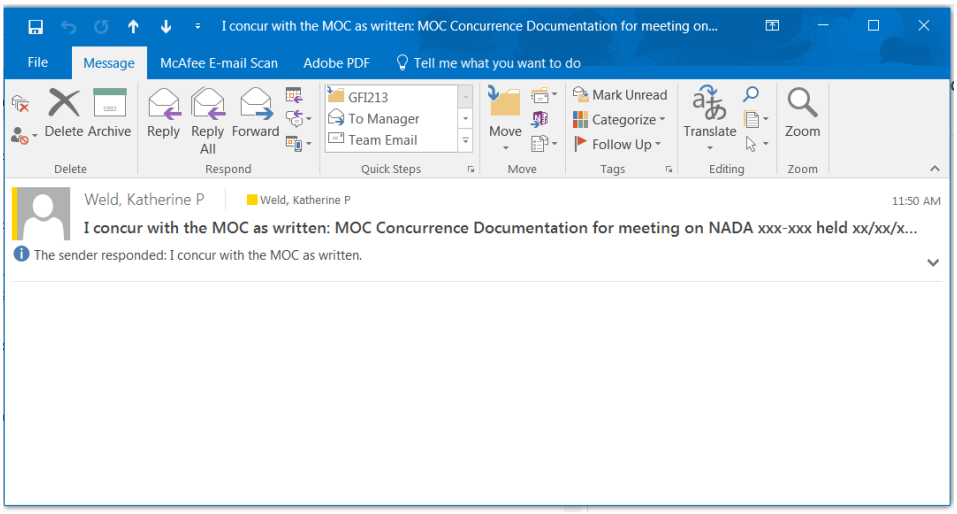
   Please respond accordingly using the buttons at the top of the email labeled:

   Concur with the MOC as written; Concur with the documents if the provided revisions are made

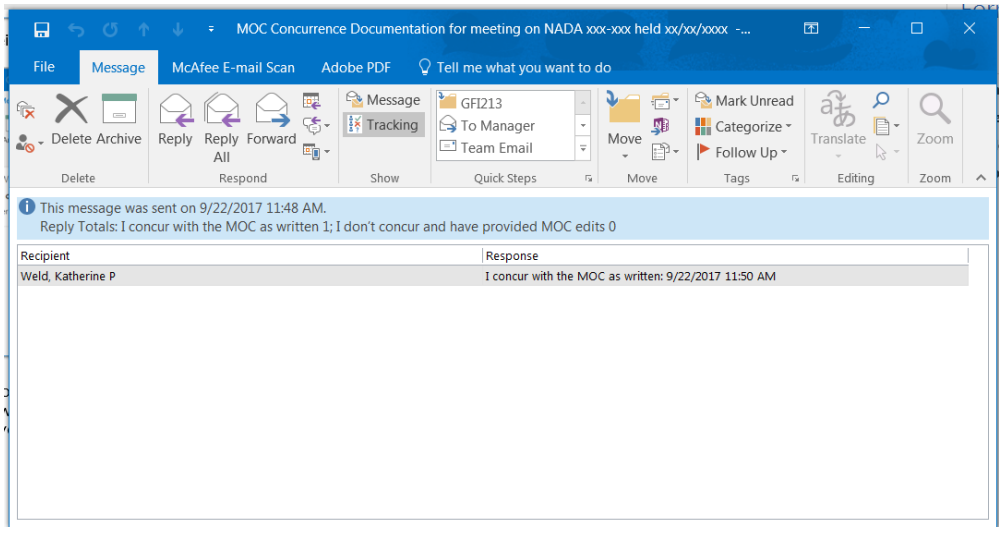
5. When someone receives your email and they select the Vote option at the top of the email, they will see the following:



6. When someone replies, you'll receive an email that looks like the picture below. Click on the notification with the "i" symbol that says, "The sender responded:" and an option to allow you to "View Voting Responses" will appear. If a person concurs with revisions, they need to provide edits that would result in their concurring on the MOC.



7. Select the "View Voting Responses" and you will see a list of all the recipients of your email requesting concurrence and the responses. In this window shown below, chose Print under the File menu. Select the print style as "Memo Style", which will include the original emailed instructions and a list of results at that point in time. Select "Adobe PDF" from the printer drop-down list and click the OK button.



8. When you are creating the PDF in the "Save PDF File As" window that appears, choose a descriptive file name (e.g., Documentation of MOC Concurrence for Z-xxxx, dated xx/xx/xxxx) and click the save button. This PDF file will be the concurrence record for the MOC. Upload an electronic copy of this PDF file into

Appian as "Other Review Related Files" when you are closing out the meeting request. An example of the PDF documentation in the "Memo Style" format is shown below.